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Breast Cancer Treatment: A Prospective Study

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**ANNUAL REPORT FOR GRANT NUMBER DAMD17-96-1-6292**

**Menstrual Cycle Maintenance and Quality of Life after Breast Cancer Treatment:  
A Prospective Study  
Jeanne Petrek, MD**

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## **INTRODUCTION**

### **MENSTRUAL CYCLE MAINTENANCE AND QUALITY OF LIFE: A PROSPECTIVE STUDY**

#### **INTRODUCTION**

The frequent morbidity associated with most cancers and their treatments make the measurement of health-related quality of life a critical mechanism for determining the toll of the entire disease. Young breast cancer patients additionally may face treatment-induced menopause and with it may experience hot flashes, mood changes, sleep disturbances, vaginal dryness, and the cascading effect of anxiety and depression. In the United States, Wake Forest University has particular expertise in quality of life with naturally occurring menopause. Wake Forest is the Coordinating Center in this issue for the Women's Health Initiative, funded by the National Institute of Health, which has accrued more than 163,000 study subjects.

Very little is known about the incidence, onset, time course, and symptomatology of premature menopause induced by breast cancer therapy. No prospective study exists. The purpose of the present study is to identify determinants of treatment-related amenorrhea and its effect on quality of life in a cohort of young breast cancer patients.

## **BODY**

### **STATEMENT OF WORK**

#### **Task 1. Months 1-2**

##### **a) Focus groups for final questionnaire wording**

Focus groups were held at Wake Forest University under the direction of Dr. Sally Shumaker, the Principal Investigator of the clinical coordinating center. As well as the wording for the baseline data questionnaires, the proposed procedural sequences were decided with attention to the women's preferences for baseline and follow-up procedures.

See work output in the revised annual report 1998. This Manual of Procedures contains more than 200 pages and consists of chapters on organizational structure; protocol; recruitment prescreening and eligibility; consenting process; baseline data collection visits; collecting participant information; chart review forms; study data forms and questionnaires; instructions for menstrual diaries; follow up contacts; data management; and quality control. This assures that the research study procedure is conducted absolutely identically in accruing women throughout the country.

Done as reported in the revised annual report 1998.

##### **b) Pilot calendar and questionnaires in Texas and New York City population**

The questionnaires and menstrual bleeding calendars were tested on non-protocol patients in Texas and New York City and were found to be satisfactory. This included follow up forms for baseline data and questionnaires, for six-month follow-up and for one-year follow-up attached in the revised annual report 1998.

Done as reported in the revised annual report 1998.

##### **c) Hire personnel.**

Personnel were hired on schedule and within the budgeted salary amount.

Done as reported in the revised annual report 1998.

##### **d) Keep lists of potential patients.**

Patients were identified from registrations of various services within each of the hospitals: Surgery, Radiation Therapy, Medical Oncology, Psychiatry, Nutrition and General Medicine.

Done as reported in the revised annual report 1998.

Patients continue to be accrued through lists maintained in the various services within Memorial Sloan-Kettering Cancer Center.

## **Task 2. Months 2-24**

### **a) Identify and Enroll patients – Time Line Amended**

As noted, by September of 1998, 185 patients had been enrolled. This was considerably less than half of the targeted accrual by Month 9 after accrual began and steps were taken to increase the self-referral patients, as noted in the body of the revised annual report 1998.

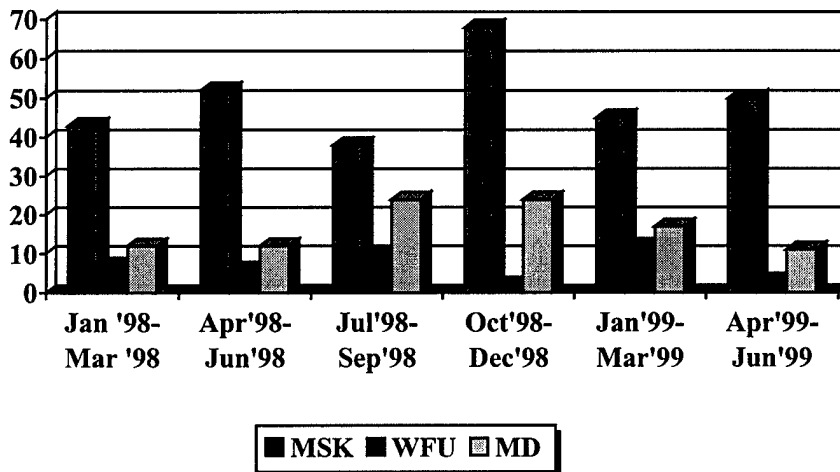
By September 1999, 456 patients had been enrolled in the study. This was less than the original targeted accrual numbers. Lt. Col. J. Pearson of the Office of Regulatory Affairs granted an extension for continued accrual.

See the 1997 annual report for the organization of research activities which continues. The past year has been devoted to recruitment and accrual that began initially on January 1, 1998. In 1998 (as stated in the 1998 annual report) self-referral was added to the recruitment strategies because of insufficient study subjects. Media attention has led to a constant level of inquiries and steady recruitment of eligible subjects. A consistent number of patients have been recruited through this method or hospital tumor and surgical registry.

Monthly conference calls take place between all centers so that staff members have the opportunity to ask questions and present potential problems to the study's principal investigators. Due to a severely diminished versus predicted recruitment number, Judy Bahnson of the Coordinating Center conducted a site visit at MD Anderson in September of 1998. In order to maintain professional and knowledgeable staff, specific areas were observed and recruitment was assessed. See Appendix A for the Site Visit report.

Besides Memorial Sloan-Kettering, the other institutions have maintained low accrual numbers and as a result, funding for recruitment staff at Wake Forest and MD Anderson has been reallocated as of August 1999. See below for a table displaying quarterly recruitment numbers for individual institutions. Memorial Sloan-Kettering has extended its recruitment date in an effort to recruit more study subjects. Since the process of accrual has changed from the inception of the study, we are planning an executive meeting at Wake Forest in January 2000. This trip will be financed with philanthropic funds from private donors. The necessary sample size will be re-calculated based on the current number of study subjects and on the number who are no longer study subjects due to death or refusal to continue participation. Analysis of key variables from the first 450 participants will more accurately predict the necessary sample size. It may not be necessary to accrue 800 women. After the re-calculation, estimates will be made about the length of accrual period.

### Participant Accrual



Memorial Sloan-Kettering will continue to recruit through tumor registries, physician referrals, and self-referrals. Wake Forest and MD Anderson will finish follow up for existing patients but will not recruit. In addition, further strategies have been implemented to recruit self-referred patients. One or more of the following strategies has been utilized in recruiting participants into the study:

1. Patient Identification through Tumor and Surgical Registries.

Once women with stage 1-3 breast cancer have been identified, the patients' oncologists/surgeons are contacted by clinic staff to obtain approval to approach the patient. If the physician approves, the patient is approached at the clinic site, or the patient is sent a letter describing the purpose of the study, which will be followed by a telephone call. Approval was obtained from the IRB for permission to make follow up calls to these patients. The clinic staff person will screen the person to ensure she meets the eligibility criteria, and then will ask the patient to participate in the study if she is eligible.

2. Referral through Physicians.

The clinical center's participating investigators, oncologists, surgeons, and radiologists also identify participants. In most instances, these physicians will have already explained the study to the participant, and the clinic staff contacts the patient to invite her to participate in the study. The patient is screened to ensure that she meets all eligibility criteria.

3. Self-Referral

Women may hear about the study through the many strategies that have been implemented to recruit participants nationally. They are screened for study eligibility, and asked to join the



study if the eligibility criteria are met. The patients will sign the informed consent, a medical record release, and will complete all baseline study questionnaires. Recruitment strategies that have been implemented are listed below:

A. Magazine and Journal Features

**MAMM Magazine** A one page advertisement was placed in the August/September 1998 issue of *MAMM* magazine, with a subsequent half-page in the October/November 1998 issue (Appendix B). *MAMM* is a bimonthly magazine targeted to those whose lives have been impacted by breast and reproductive cancers. Issues include information on the latest treatments, inspiring stories of survivors, and controversies surrounding a cancer diagnosis.

*MAMM* guarantees a circulation of 70,000 copies through four venues. 35,000 copies are distributed through major bookstore chains and newsstands. Currently, there are approximately 7,000 regular subscribers to the magazine, with an additional 10,000 copies that go to randomly selected persons from lists of women who have expressed an interest in cancer related issues. 15,000 copies are distributed to 274 different breast care organizations, support groups, physicians' offices, and activist organizations who have requested copies. The following is a geographic breakdown of *MAMM*'s circulation from a subscriber profile conducted in March of 1998 by the Polk Company:

CENSUS DIVISION	%	CENSUS DIVISION	%
East North Central	23.1%	Pacific	11.2%
East South Central	2.0%	South Atlantic	15.2%
Middle Atlantic	25%	West North Central	4.7%
Mountain	4.9%	West South Central	7.5%
New England	5.6%	Unknown Census Division	0.7%

In addition to this paid advertisement, in May of 1999, *MAMM* featured Dr. Jeanne Petrek in two articles. In each of these articles the study was mentioned for eligible participants. (See Appendix C)

**Glamour Magazine** In the July edition of *Glamour* magazine, a young woman diagnosed at age 24 with breast cancer was featured in a Special Women's Health Series. The article focused on young women diagnosed with the disease and discussed issues such as subsequent pregnancy and premature menopause associated with chemotherapy. (Appendix D) The study, along with contact information, was listed for eligible participants.

*Glamour* is marketed towards the contemporary woman, informing on current

fashion and beauty trends as well as on important health issues for women. The territorial distribution for circulation is listed below.

Pacific	292,878	East South Central	110,121
New England	116,199	East North Central	318,325
Middle Atlantic	294,128	West North Central	145,557
South Atlantic	337,070	West South Central	185,454
Mountain	115,179	Canada	82,703
Foreign	20,001	Other	9,038

***Cancer Control – Journal of the Moffitt Cancer Center*** Dr. Jeanne Petrek published an article pertaining to “Pregnancy after Breast Cancer” in the May/June 1999 volume of this medical journal (Volume 6, No. 3). (Appendix E) To inform physicians of this study for appropriate referrals, the study and grant information are listed.

This peer-reviewed journal is published six times a year and is delivered at no charge to about 28,000 medical professionals. These professionals include oncologists, primary care physicians, and medical researchers specializing in oncology.

**B. Organizations Displaying Brochures**

Brochures were distributed to the following support group organizations for display:

**The Susan G. Komen Breast Cancer Foundation** - This organization is dedicated to advancing research, education, screening and treatment of breast cancer. Nancy Goodman Brinker established the foundation in 1982, in honor of her sister Susan Komen who died of the disease. It is the nation’s largest private funder of research dedicated solely to breast cancer, raising more than \$90 million dollars since being founded. The Komen Foundation is best known for its sponsorship of *Race for the Cure*, an annual run/walk held in October to raise money for breast cancer.

Two hundred brochures were initially distributed to the foundation for display at various locations including support group meetings and at the annual *Race for the Cure*. Additional brochures are sent to the organization as needed.

**Y-ME** - This national breast cancer organization was founded in 1978 by two breast cancer patients. It was established to provide information and support to those touched by the disease. They maintain 24-hour toll free hotlines for both English and Spanish speaking women who need support. Y-ME has many local chapters that run open door groups, early detection

workshops, survivor groups, and many other support programs.

Five hundred brochures were initially distributed to Y-ME for display. Additional brochures are distributed as needed.

**SHARE** - Self-help for Women with Breast or Ovarian Cancer - This self-help organization serves women, men and children affected by breast and ovarian cancer. They promote public awareness and early detection. They place special emphasis on wellness programs dedicated to reducing stress, healthy diets, imagery, and exercise.

SHARE-A-WALK is an annual 4-mile walk held to raise funds for breast and ovarian cancer. Last year at its eighth annual walk held in Central Park in New York City, 100 brochures were made available to the public. In addition, brochures will be made available this year for the annual walk. SHARE also puts brochures on display at meetings and workshops held for breast cancer patients.

The SHARE organization has an annual newsletter that is sent out to members and health care professionals quarterly. In their fall 1999 newsletter (Appendix F), SHARE listed the study under the section Medical Updates. Included in this section are current breast cancer and ovarian studies and results from past studies.

These brochures will remain available at these organizations, and may increase self-referral as public awareness of the study continues to increase.

#### C. Newspaper Advertisements

***Our Town*** – In the December 2, 1998 issue of this weekly paper, an advertisement was placed regarding the study and eligibility criteria (Appendix G). This free paper is distributed in doorman apartment buildings, retail establishments, banks, and hundreds of street news boxes throughout the East Side of Manhattan, NY (14<sup>th</sup> Street to 96<sup>th</sup> Street). Its circulation is 55,000.

***Manhattan Spirit*** - This same ad was placed in the December 3, 1998 issue of this paper (Appendix H). With a circulation of 50,000, it is distributed throughout the West Side of Manhattan from Houston Street to 116<sup>th</sup> Street. Similar distribution methods to those of *Our Town* are used.

***Riverdale Review*** – An additional advertisement (Appendix I) was placed in the December 3-9, 1998 issue of this paper. Its current circulation rate is 20,000 and is distributed throughout the northwest Bronx area of New York City.

In combination, these three local papers cover a large portion of New York City. All three newspapers are distributed from News Communications, Inc. Each is circulated to customers without charge and readers are estimated to be 60% female with a median age between 35 – 45 years of age.

***The New York Times/Healthy Living*** – Each Tuesday in the *New York Times* there is a *Healthy Living* Section. This section focuses on current health issues and has an area specifically

devoted for these types of advertisements. Under the title *Research Studies*, a classified advertisement was placed for the study (Appendix J). This section is distributed nationwide and the following are some demographic information on the paper's readers:

- Nationwide Circulation – 2.9 million
- Median age of reader – 44
- Sex of reader - 57% male - 43% female
- 78% have a college degree
- Median income is \$83,887
- 54% have professional jobs

#### D. Web Pages and Newsletters

**Memorial Sloan-Kettering Cancer Center** -The web page established on the Memorial Sloan-Kettering Cancer Center web site has been modified. (Appendix K) The information on the page has not changed, however with the help of a public relations specialist at Memorial Sloan-Kettering the layout of the ad was altered with the goal of attracting additional participants. The page was initially activated August 31, 1998 and is located in the cancer and treatment section of the web site.

Memorial Sloan-Kettering also has a center-based newsletter for employees. It is distributed in hard copy to employees and is also accessible through the intranet web site. In the June 1999 issue, Dr. Petrek was featured in the MSKCC Interview section (Appendix L). In this interview she discusses the study and its relevance to breast cancer survivors. Since this newsletter is sent to all employees, including physicians, appropriate referrals can be made for participation.

**Cancer Care, Inc.** - Additionally, the web page is linked to the web site of Cancer Care, Inc. This organization is a resource for people diagnosed with all types of cancer and offers counseling support, cancer information, referral services, and financial support to these patients. The page is linked to their breast cancer and sexuality section.

**Breast Cancer News Daily** - Breast Cancer News Daily also provided information regarding the study in their December 1998 newsletter (Appendix M) and September 1999 newsletter. This newsletter is available on their web site at <http://www.breastcancer.net>. The BCN newsletter is also delivered in hard copy, free of charge to over 3,300 breast cancer survivors, health professionals, and legislators in 54 countries. An advertisement banner has also been placed on their web site since December of 1998(Appendix N) allowing interested viewers to link to the study's web page.

**NABCO (National Alliance of Breast Cancer Organizations)** - NABCO established in 1986, is a non-profit resource for information and education about breast cancer. It is a network of more than 375 organizations providing detection, treatment, and care to women. Its quarterly newsletter is available on both hard copy and online at their web site <http://www.nabco.org> . In April 1999 (Volume 13, Number 2), information regarding the study was placed in NABCO News (Appendix O).

In addition to these links, several other web sites are being pursued. Dr. Susan Love, MD has just established a brand new web page for patients on which we hope to establish a link to.

We will continue to advertise in the BCN newsletter and other web sources as we have had a very positive response to this recruitment strategy.

**Oncology News** – In the November 1998 (Volume 7, No. 11) issue of *Oncology News*, (Appendix P) information regarding the study and how to participate were included. This newsmagazine is published by the journal *Oncology* and is circulated monthly. Issues are distributed at no charge to health professionals in oncology and related fields.

#### E. Physician Letters

Physician organizations were targeted as an additional recruitment resource. Merge mailings were sent to the New York Metropolitan Breast Cancer Group, Inc., The American Society of Breast Disease and The Association of Women Surgeons. Physicians were sent a letter, brochures, and information about the purpose of the study. Letters were initially sent out in 1998 and then again in 1999. Letters were contained in the Appendix of the Revised 1998 Annual Report.

**New York Metropolitan Breast Cancer Group, Inc.** - 1998 marked the 25th anniversary for this organization. It is a tri-state society for physicians involved in the treatment of breast cancer. Each physician was sent a letter explaining the study and asking for his or her assistance with recruitment. At least three brochures were included with each letter in both mailings.

**American Society of Breast Disease** - A group of physicians founded this society in 1977 for those interested in studying diseases of the breasts. It was expanded into a multi-disciplinary organization in 1980. The group has more than 600 members representing 44 states and 16 foreign countries. 21 different specialties related to the breast are represented. A similar letter was sent along with five brochures to 404 physicians. Listed below is a geographic and specialty breakdown of letters sent.

SPECIALTY	TOTAL	SPECIALTY	TOTAL
Surgery	253	Administration	2
Medical Oncology	55	Genetics	1
Radiology	37	Preventive Oncology	1
Radiation Oncology	21	Emergency Medicine	1
Ob/GYN	8	Family Practice	1
Internal Medicine	7	Public Relations	1

<b>GEOGRAPHIC LOCATION (U.S. TIME ZONES)</b>	<b>TOTAL</b>
Eastern	183
Central	138
Mountain	11
Pacific	72

**Association of Women Surgeons** - A third letter was sent out to members of The Association of Women Surgeons (AWS). AWS was established in 1981 to promote the growth and advancement of female surgeons. They have over 890 regular members representing every surgical specialty. Membership includes women from every US state and international members from Canada, Mexico, Europe, and Asia.

The Clinical Coordinating Center at the Wake Forest School of Medicine continues to monitor recruitment and issues monthly recruitment reports to each participating institution. The strategies listed above were developed to assist the clinical centers in meeting their recruitment goals.

b) Write annual report.

1998 report completed and revised.

1999 report completed.

### **Task 3. Months 8-45**

a) Mail out and receive back study calendars and other data instruments.

Questionnaires and menstrual calendars have been received on schedule for 6-month follow up. At the time of September 1998, less than 10 patients had been followed for the 6-month figure and, therefore, results containing follow-up will be quoted in the October 1999 Annual Report.

See the next section for current follow-up figures.

b) Enter data in ongoing fashion.

Such data has been entered in an ongoing fashion and such data is presented in the tables below. The charts below list demographics of the 456 patients collected as of September 15, 1999.

	Sloan-Kettering	MD Anderson	Wake Forest	All Clinics
<b>Marital Status</b>	<b>N</b>	<b>N</b>	<b>N</b>	<b>N</b>
Never Married	53	9	5	67
Presently Married	207	83	37	327
Marriage-like relationship	19	5	0	24
Divorced/separated	20	12	3	35
Widowed	0	0	1	1
No Response	2	0	0	2

	Sloan-Kettering	MD Anderson	Wake Forest	All Clinics
<b>Race</b>	<b>N</b>	<b>N</b>	<b>N</b>	<b>N</b>
White	267	86	39	392
Black/African American	12	10	7	29
Hispanic	10	9	0	19
Asian/Pacific Islander	11	4	0	15
American Indian/Alaskan	1	0	0	1

	Sloan-Kettering	MD Anderson	Wake Forest	All Clinics
<b>Education Level</b>	<b>N</b>	<b>N</b>	<b>N</b>	<b>N</b>
Grade School (1 <sup>st</sup> -8 <sup>th</sup> )	1	0	0	1
Some High School	2	3	2	7
High School Diploma/GED	20	12	9	41
Bus./Vocational Training	10	3	7	20
Some College	39	21	9	69
Associates Degree	25	4	3	32
College Graduate; BA, BS	82	36	7	125
Some College/Professional	32	13	2	47
Master's Degree	70	14	6	90
Doctoral Degree	20	2	1	23
No Response	0	1	0	1

	Sloan-Kettering	MD Anderson	Wake Forest	All Clinics
<b>Occupation</b>	<b>N</b>	<b>N</b>	<b>N</b>	<b>N</b>
Unemployed	99	41	15	155
Professional/Technical	105	34	12	151
Manager/Administrator	40	6	5	51
Clerical	19	11	9	39
Sales	13	6	0	19
Service	4	2	0	6
Skilled, service repair	1	0	1	2
Laborer	0	0	1	1
Farmer	1	1	0	2
Military	1	0	0	1
Other	18	8	3	29

	Sloan-Kettering	MD Anderson	Wake Forest	All Clinics
<b>Religion</b>	<b>N</b>	<b>N</b>	<b>N</b>	<b>N</b>
Catholic	138	31	3	172
Jewish	44	3	0	47
Protestant	75	52	41	168
Muslim	2	0	0	2
Greek Orthodox	1	0	0	1
Russian Orthodox	1	0	0	1
Buddhist	1	0	0	1
Other	12	12	1	25
None	26	11	1	38
No Response	1	0	0	1

	Sloan-Kettering	MD Anderson	Wake Forest	All Clinics
<b>Age</b>	<b>N</b>	<b>N</b>	<b>N</b>	<b>N</b>
18-25	3	0	0	3
25-30	13	5	1	19
30-35	46	16	5	67
36-40	83	30	12	125
41-46	155	58	28	241
Missing	1	0	0	1



## Preliminary Data

Social questionnaires including the arm swelling scale and the menstrual cycle calendars are obtained every 6 months. Since accrual is not complete, we have preliminarily analyzed only a small amount of data for this annual report as follows. In the Medical Outcomes and Symptoms®, Rand Corporation questionnaire, participants are asked to indicate whether they are currently experiencing the symptoms given below. Physicians are interested in the symptoms that patients experience and for how long they experience them, however, often patients do not mention these unless specifically asked. These preliminary statistics indicate some of the more prevalent symptoms of these participants and the proportion noting their occurrence over the first year.

Symptoms	Baseline (%)	6 Months (%)	12 Months (%)
Fatigue or low energy level	87	81	75
Restless sleep	78	67	62
Mood changes	64	62	56
Feeling depressed	64	57	45
Decreased efficiency	59	44	31
Difficulty concentrating	57	49	42
Forgetfulness	54	60	55
Lowered work performance	54	35	17
Headaches	53	41	45
Constipation	52	37	22
Loss of interest in work/activities	52	37	20
General aches and pains	51	56	45
Short temper	49	50	39
Muscle pains/aches/cramps	49	48	44
Breast sensitivity/tenderness	46	53	47
Avoidance of social affairs	43	28	11
Vaginal dryness	41	45	42
Lightheadedness when standing up	41	31	28
Nervousness or shakiness inside	39	37	29
Weight gain	37	52	44
Night sweats	37	46	43
Increased appetite	37	40	35
Bloating	35	30	30
Abdominal pain/cramps	35	30	27
Diarrhea	33	25	19
Hot flashes	32	55	51
Sleeping too much	32	24	16
Joint pains	31	40	40
Aches in back of neck and skull	31	32	30
Decreased appetite	31	12	3

Mouth ulcers	29	14	10
Weight loss	26	15	11
Blind spots, fuzzy vision	21	14	20
Faintness or dizziness at rest	14	12	7
Difficulty healing	14	10	4
Swelling of ankles or feet	11	19	13
Cold sweats	10	10	3
Feelings of suffocation	10	9	7

The Beck Depression scale is used widely in research to determine depression in patients. In the questionnaire, this scale is listed under the title “emotional feelings.” The following is a listing of scores of the participants who scored some level of depression. Participants under 16 are not listed because this is scored as no depression in the Beck. Participants who score between 16 and 22 are considered mildly depressed. Those scoring between 23-27 are considered moderately depressed, between 28-32 more seriously depressed, and higher than 32 are regarded as severely depressed.

<b>Beck Depression Scores</b>	<b>Baseline</b>	<b>6 Month Follow-up</b>	<b>12 Month Follow-up</b>
<b>16-22</b>	48	27	4
<b>23-27</b>	14	6	1
<b>28-32</b>	4	4	0
<b>&gt;32</b>	4	1	1

In addition to this information, the data presented below represents further information followed by the study.

	<b>Baseline (n=448)</b>	<b>6 Months (n=281)</b>	<b>12 Months (n=114)</b>
<b>Reoccurrences</b>	None	10	4
<b>Pregnancies</b>	None	4	1
<b>Births</b>	None	None	1
<b>Swelling in arm or hand</b>	74	62	25

<b>Clinic</b>	<b>MSK</b>	<b>WFU</b>	<b>MD Anderson</b>
Participants Dropped From the Study	11	4	1
Participants Who Have Died	4	1	1

c) Crosscheck data and clean.

This is ongoing and has proceeded according to plan.

## Data Monitoring and Tracking

The Coordinating Center performs editing procedures to ensure the quality of the data collected by the Clinical Centers. These are as follows: 1) initial screening of the data, using logic and range checks that are built into the data entry system and 2) edits which assess the serial integrity of the data.

Much of the data collected from study subjects comes from regularly scheduled mailings. Time windows have been defined for these scheduled mailings. A tracking system has been developed to facilitate on-time collection of data. In May 1999, the following approach was implemented to contact participants with forms due: A postcard was first mailed followed by two rounds of phone calls if the forms had not been returned 2 weeks after the postcard had been mailed. One month later, of 156 women contacted, 36% had returned the missing forms after the first round of calls and the second call yielded just a few more. So, in June 1999, the second round of calls was eliminated. One month later, of 285 women contacted, 40% had returned missing forms. To increase further the return rate of late forms, we stopped sending postcards and contacted the participants immediately if a form was late. We continued calling until the participant was reached on the phone. In July, August and September, 79, 237 and 84 phone calls were made respectively. In addition, we hired a nighttime/weekend interviewer. Often these women are very busy and are more easily contacted through phone interviews during these times.

We also developed a newsletter (Appendix Q) that was mailed to participants in July 1999 with a copy of the book Women and Cancer co-authored by Dr. Jeanne Petrek (Appendix R). Finally we are in the process of developing an incentive program that will start in January 2000 that would reward patients who return their forms promptly. We have been very active in tracking the participants to get rapid responses.

## Follow-up of Participants

### 6-Month Questionnaire

Due	372
Completed	290 (78%)
On Time	147 (51%)
< 1 month late	49 (17%)
1 – 1.9 months late	42 (14%)
2 – 2.9 months late	34 (12%)
≥ – 3 months late	18 (6%)

### 12-Month Questionnaire

Due	219
Completed	133 (61%)
On Time	57 (43%)
< 1 month late	30 (23%)
1 – 1.9 months late	21 (16%)
2 – 2.9 months late	19 (14%)
≥ – 3 months late	6 (5%)

d) Write annual report.

October 1998 Annual Report completed.

October 1998 Annual Report revised.

October 1999 Annual Report completed.

October 2000 Annual Report in progress.

## **KEY RESEARCH ACCOMPLISHMENTS**

**NONE – Still accruing study participants**

## **REPORTABLE OUTCOMES**

**NONE – Ongoing Research**

## **CONCLUSIONS**

**NONE**

## **References:**

Menstrual Cycle Maintenance and Quality of Life After Breast Cancer Treatment: A Prospective Study

**None**



## Appendix A

DOD Site Visit  
MD Anderson Cancer Center  
Houston, Texas  
September, 1998

The MD Anderson DOD Breast Cancer and Menstrual Cycle Maintenance Clinical facility was visited on September 8 and 9, 1998. The Site Visit was the first for the study. The clinic staff are professional and are knowledgeable about the Protocol and the manual of Operating Procedures and dedicated to implementing it. The purpose of the Site Visit was to observe clinic operations and the recruitment process, foster communication and promote adherence to the Protocol. Specific areas observed are listed as follows:

- 1) Staffing Patterns
- 2) Facilities
- 3) Recruitment
- 4) Data collection procedures
- 5) Visit flow

The Site Visit was conducted by Judy Bahnson from the Coordinating Center. Screening visits were scheduled for that day. In addition to the items reviewed on the attached check list, the following observations were made.

### Personnel

MD Anderson has nurses that specialize in particular cancers. Julie Alderfer and Susan Binkly are the breast nurses. Eva Singletary is Chief of Surgical Breast and the Principal Investigator at this Clinical Site. Shine Chang is co-investigator and Principal Investigator of the Ancillary Study on dietary and anthropometric influence on menstrual cycle maintenance and quality of life after breast cancer.

Julie Alderfer, RN, is the DOD Clinic Coordinator for the study at the MD Anderson Cancer Center. She is funded 50% on the DOD Menstrual Cycle Maintenance and Quality of Life Study. She identifies and recruits participants from surgery, radiology, oncology, and the breast center as well as through their tumor registry. Julie has daily access to all patients scheduled for clinic visits and participates in the multi disciplinary patient management team conference. She explains the study to participants, obtains informed consent and is responsible for all activities involving data collection, including contact with outside physicians. All DOD data collection forms are reviewed by Julie prior to sending them to the Data Coordinating Center and participants are contacted as needed for clarification of data or missing information. Errors and missing data are uncommon for this site.

In addition to the DOD study, Julie is involved with a lymph mapping/sentinel lymph node biopsy study with six referring surgeons. They designate the patients, Julie schedules all pre-surgery tests, obtains informed consent and assists the surgeons in the operating room several days per week. This study recruits patients prior to treatment and does not compete with the DOD protocol.

Susan Binkly, RN, is the Clinic Coordinator at MD Anderson and serves as back-up for Julie Alderfer. She has an understanding of the study protocol and is familiar with the Manual of Operating Procedures and participated in the central training session at the coordinating center. At least one nurse is always available to see scheduled patients.

The demands of the daily clinics, surgery and research studies have the potential for creating time conflicts for Julie Alderfer. The DOD study requires considerable tracking of patients and follow-up phone calls. In order to provide additional time for Julie Alderfer, Susan Binkly will be taking over the Thursday and Friday Clinics/OR for Julie. The recommendation was made that Julie check with the MD Anderson volunteer office to see if a volunteer could assist her several hours per week with some of the DOD study tasks such as making copies of forms, filing, addressing participant letters, etc. so that more of her time can be used for recruitment activities and follow-up phone calls.

#### Space and Accessibility

The space dedicated for the study is conducive for efficient operation. The clinic area as well as staff offices are all located in one building providing easy access for both staff and participants. The Clinic consists of a large comfortable waiting area and treatment rooms. Several rooms are available for patient education or conferences so that patients have a private area to discuss the study and fill out data collection forms. Office space for clinic staff is located close to the clinic area. Both nurses have computers and software to access patient information and tracking.

#### Recruitment

Recruitment at MDAnderson has been less than anticipated given the initial estimated pool of 750 women aged 45 years or younger that were identified at the onset of the study. In addition, it appeared from an earlier recruitment report that the refusal rate was unusually high for this clinic site. Therefore, considerable time was spent in reviewing past patient lists to resolve this discrepancy and assist in tracking and recruitment efforts. The following table summarizes the recruitment process to date:

Total Patients Screened $\leq$ 45 years old	750
---	-----

Patients Ineligible

Irregular Menstrual Cycles	22
No menstrual cycles	5
Hysterectomy	28
Stage IV malignancy	22
Reoccurrence/Previous malignancy	23
Non English speaking/non-U.S. residents	28
Psychiatric/psychological problems	3
Diagnosed > 6 months	<u>516</u>
Total Ineligible	647

Patients Eligible

Consented	46 (45%)
Refused	5 (5%)
Pending	<u>52 (50%)</u>
Total Eligible	103

The following points are important to note:

1) Clearly the original estimated numbers did not accurately reflect the patient pool. Of the 750 women identified 594 should not have been included. I suspect the report from the MD Anderson tumor registry did not control for Cancer Stage, Previous Malignancy or  $\geq$  6 month diagnosis.

2) The IRB process at MD Anderson is lengthy. When the protocol was changed to allow the study to capture patients diagnosed within an 8-month window, additional women were lost in the two-month period. IRB approval to go to the 8-month window was not approved until September 1, 1998. The process from submittal to approval was several months and many women were lost to recruitment because of the time window.

3) Many patients at MD Anderson are undergoing hysterectomies as part of their breast cancer treatment which also impacts on the recruitment.

4) The original tracking system made it difficult to know who was contacted and where the individual was in the study pipe line. The tracking system has been revised so that Julie can quickly see who is eligible, what the window is, if a letter was mailed or contact was by phone or in the clinic and if a follow-up call is needed. A copy of this appears in the appendix.

5) In a self-evaluation discussion of perceived weaknesses in the area of recruitment, Julie Alderfer indicated that her weakest area was the follow-up phone calls and the need to sometimes "sell the study." Julie suggested that because she was not quite comfortable making these calls that sometimes she found other things to do and put the calls on the back burner. In preparation for the site visit she found that she had missed the window on several participants and is now

very aware of the importance of the follow-up calls. We developed multiple scripts to guide her through this process with suggestions for several types of situations such as: what to say when you approach a participant for the first time particularly over the phone, and scripts to use when a participant has not returned the forms. We did some role playing to increase Julie's comfort level. In order to counter the avoidance problem, Julie and Dr. Singletary have dedicated Friday as the day to do all follow-up phone calls to patients. I feel sure that as Julie makes more calls she will become much more efficient and that the process will be easier. The Coordinating Center will include several chapters from the book "Motivational Interviewing" for Julie's use. In addition to these follow-up phone calls Julie will re-contact all women who refused that are still within the window. She also plans to call those women with irregular periods who are under 40 to see how they are defining irregular. In the event these women are having menstrual cycles every 4-6 weeks, then she will make every effort to recruit them into the study. Additional strategies for recruitment were discussed including: newspaper articles, special interest stories and the yearly Breast Cancer Forum as well as other physicians.

### Informed Consent

Julie Alderfer was observed explaining the study and obtaining informed consent with a participant. She was knowledgeable about the study and the consent process and was relaxed with the participants. She followed the procedures outlined in the Manual of Operating Procedures. No problems were noted however it was suggested that informed consent be done in a patient education room or conference room to ensure complete privacy.

### Summary

The MD Anderson Cancer Center staff are dedicated, pleasant and professional. They communicate enthusiasm for the DOD Breast Cancer Study and have good rapport with the participants. The staff seems committed to maintaining and improving the implementation of the protocol. With some additional practice on interviewing techniques, I feel they can become a stronger more competent research team.

### Action Items

1. Check on the possibility of having a volunteer help with copying study material, etc.
2. Susan Binkley to take over Thursday and Friday clinics to free up additional time for Julie.
3. Julie to make follow-up calls on Friday.
4. Julie to contact those patients that refused who are still within the window to see if they might agree to participate at this time.

DOD Menstrual Cycle maintenance and Quality of Life Clinic Monitoring Visit  
Check List

Task	Reviewed	Comments
<b>Personnel</b> Review of Staffing Patterns Division of Work Recruitment Interviews Informed Consent Data Form Review Quality Control	✓ ✓ ✓ ✓ ✓ ✓ ✓	<i>Julia 50% - Suzanne</i> <i>INC Cost</i> <i>See main report</i> <i>Release d</i> <i>Good - Need more pre-work</i> <i>Good</i>
<b>Training and Retraining</b>	✓	<i>Role playing</i> <i>developing scripts</i>
<b>Review of Forms and Reports</b> Data Collection activities Error Reports	✓ ✓	<i>Few Errors for Site</i>
IRB Approval Document Has IRB been informed of Protocol Changes  Screening ID Assignment book	✓ ✓  ✓	<i>Plus up dates</i>
<b>Data Collection</b> Clinical Facilities Space Privacy Record Storage/Security Participant Interview Observation Informed Consent Observation	✓ ✓ ✓ ✓ ✓	<i>Great Center</i> <i>Staff Offices:</i> <i>criticals - fairly</i> <i>small 1 room</i> <i>4 people</i>
<b>Review of Records</b> Chart Reviews Informed Consent Appropriate Signatures Complete data forms Source Documents Review of Protocol Review of Manual of Procedures	✓ ✓ ✓ ✓ ✓ ✓ ✓	<i>Un</i> <i>order</i>

*JB Sept 98*

# MENSTRUAL CYCLE MAINTENANCE & QUALITY OF LIFE

MEMORIAL SLOAN-KETTERING CANCER CENTER

## WHAT IS THE PURPOSE OF THE STUDY ?

To determine how treatment for breast cancer may affect a woman's menstrual cycles and her quality of life. Questionnaires and menstrual cycle diaries are used.

## IMPORTANT FACTS TO KNOW:

- Study information will be kept completely confidential.
- Informed consent will be obtained from all study participants.
- There are no medical or health risks in participating in this study.
- No blood or urine samples are collected.
- There is no cost for participation in this study.
- Participation will not affect your medical care.
- No in-person visits are necessary to participate in this study.
- Women who have participated in previous studies report their satisfaction at making a contribution to breast cancer research.

## HOW DO I BECOME A PARTICIPANT ?

- Are you between the ages of 18-45?
- Have you been diagnosed with breast cancer, stage I, II, or III, in the past eight months?
- Were you having regular menstrual cycles at the time of your diagnosis?
- If you answered yes to these questions you are eligible to participate in this study.

## HOW DO I PARTICIPATE?

- An initial questionnaire will be sent to all women, followed by additional questionnaires every six months.
- The initial questionnaire may take 45 minutes, and subsequent questionnaires will take 20-30 minutes.
- Every woman will be provided with menstrual cycle diaries, which they will fill out for the duration of the study.

## How & When will I receive follow-up questionnaires & calendars ?

- All follow-up questionnaires will be sent to you from the Wake Forest University School of Medicine for 3 years—the duration of the study.
- Every six months, from original date of enrollment, you will be sent a new questionnaire, and every 3 months you will be sent new menstrual diaries.

## Who is involved in this study ?

- Memorial Sloan-Kettering Cancer Center in New York is conducting the study. The Wake Forest University School of Medicine in Winston-Salem, North Carolina, one of the largest centers in menopause research, is analyzing the data.
- A total of 800 women will participate in this study.





# MAMM

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# THE SECRETS ABOUT SEX

## THE SILENCE ABOUT CANCER TREATMENT'S EFFECTS ON SEXUALITY OBSCURES A COMMON SOURCE OF PAIN

In 1992, legendary sex therapist Helen Singer Kaplan, MD, PhD, wrote that "the potentially devastating sexual consequences of the adjuvant treatments for breast cancer have been virtually ignored."

Diagnosed with breast cancer herself in 1988, Kaplan reported on her experience treating breast cancer survivors who complained of a near total loss of sexual desire, diminished genital sensations, and weak and difficult-to-achieve orgasms. These women said that prior to receiving chemotherapy, their sex lives had been satisfactory. Kaplan found that the women were suffering from a chemotherapy-induced deficiency of testosterone, a hormone naturally present in healthy women. When she gave her patients testosterone supplements, the women were overjoyed to find that their sexual feelings returned—some regarding it as nothing less than "a miracle."

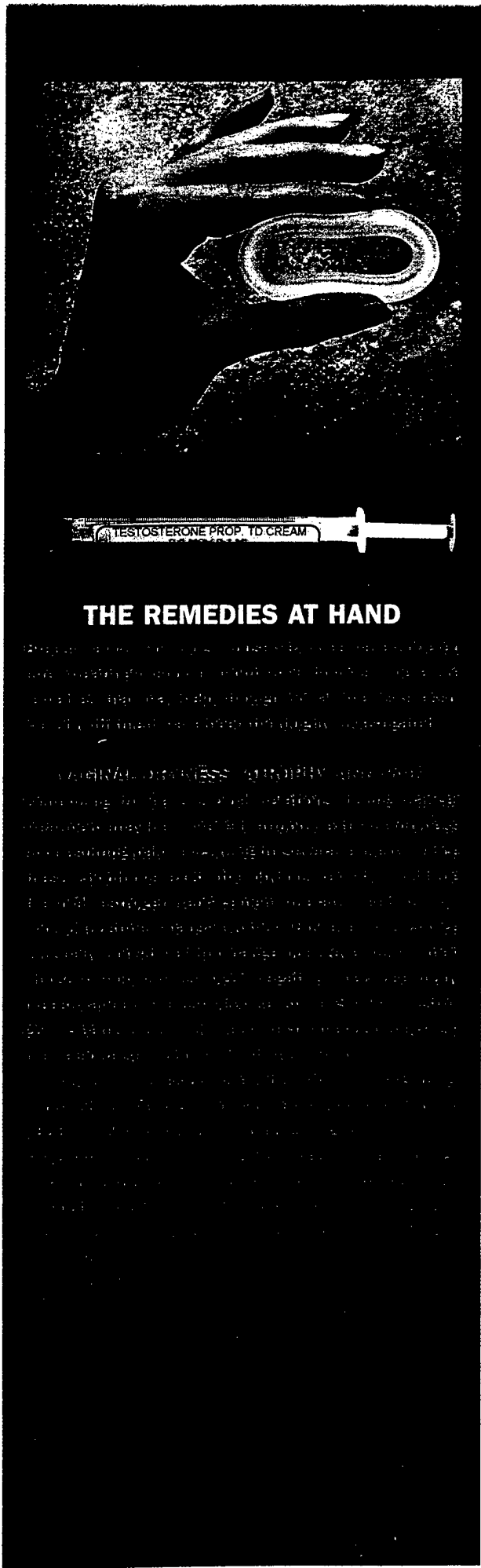
Kaplan's article, "A Neglected Issue: The Sexual Side Effects of Current Treatments for Breast Cancer," was published in the *Journal of Sex & Marital Therapy*. In contrast to these sexual side effects, Kaplan wrote the well-known and feared side effects of chemotherapy—hair loss and nausea, among others—"are bearable because they are time-limited and reversible."

Kaplan died of cancer in 1995. If she were alive today, she would find that despite her plea that oncologists, gynecologists and nurses pay attention to cancer survivors' sexual health, change has been slow in coming.

Along with a review of the medical literature, interviews with survivors and physicians show that secrecy and silence still surround the subject of sexuality after breast cancer treatments. Survivors say they are suffering from unexpected and severe physical and psycho-

BY FRANCES CERRA WHITTELEY  
PHOTOGRAPHS BY BILL STEELE





## THE REMEDIES AT HAND

Problems arise when a woman's sexual desire is reduced or when her body's natural lubrication is diminished. In some cases, the problem may be related to the cancer treatment itself. In other cases, it may be related to the aging process. In either case, the problem is real and it can be a source of frustration and distress.

**VAGINAL DRYNESS** is a common problem for women who have been treated for breast cancer. It can be caused by the cancer treatment itself, or by the aging process. In some cases, the problem may be related to the cancer treatment itself. In other cases, it may be related to the aging process. In either case, the problem is real and it can be a source of frustration and distress.

There are several ways to deal with vaginal dryness. One way is to use a lubricant. Another way is to use a hormone cream. A third way is to use a hormone pill. A fourth way is to use a hormone injection. A fifth way is to use a hormone implant. A sixth way is to use a hormone pellet. A seventh way is to use a hormone ring. A eighth way is to use a hormone patch. A ninth way is to use a hormone gel. A tenth way is to use a hormone cream.

logical changes that have destroyed their formerly satisfying sexual lives and now threaten their relationships. How many survivors have such problems is unknown. Critical research on this question and many others related to sexuality has yet to be done.

But estimates of the number of survivors with adverse sexual effects go as high as one in two. "I think it is no exaggeration that at least 50 percent end up with fairly severe problems, particularly the premenopausal women who become menopausal," says Leslie Schover, PhD, a psychologist on the staff of the Cleveland Clinic Foundation and author of *Sexuality and Fertility After Cancer* (John Wiley & Sons, 1997).

On the other hand, Patricia Ganz, MD, an oncologist and director of the division of cancer prevention and control research at the UCLA Jonsson Comprehensive Cancer Center, says a retrospective study she headed shows that women who have survived from one to five years after diagnosis "look pretty similar to healthy women of the same age who never had breast cancer in their reporting of overall sexual satisfaction." Dr. Ganz believes that some survivors with sexual problems are blaming them on their cancer treatments without realizing that the natural aging process is actually responsible. However, her study, reported in the February 1998 issue of the *Journal of Clinical Oncology*, also concluded that among the 40 percent of women who had received chemotherapy, severe vaginal dryness was contributing to poorer sexual functioning.

Ganz's report echoed Kaplan's call for physicians to inquire about their patients' sexuality, saying, "these issues are often overlooked by health care providers and traditional psychosocial support programs."

It is this lack of communication about sexual side effects that some survivors find most troubling. "I'm just astonished that they know these things happen, but they do no baseline testing, so if you say, 'I have no libido,' they can see if you have a deficiency," says Harriet Kay, who was diagnosed with breast cancer six years ago at the age of 51.

"My doctors talked about nausea and thinning hair, but nothing about menopause or sexual problems. Those problems are still with me, while the nausea and hair are all fine now," continues Kay, a secretary in Worcester, Massachusetts.

## HER BLACK CLOUD

Diagnosed three years ago at the age of 34, Lindsey Bartholomeus is one of the estimated 10 percent to 20 percent of women diagnosed with breast cancer each year who are of childbearing age.

"It's like a black cloud in my life," Bartholomeus says of her sex life. "I have no sexual desire whatsoever. I was thinking it was me, wondering if maybe I didn't love my husband anymore, but after looking at the breast cancer listserv on the Internet, I realized I wasn't alone." After undergoing a lumpectomy in March 1997, and then a radical mastectomy, she spent six months receiving chemotherapy (Adriamycin and Cytosan). Bartholomeus says she never expected to be left with sexual difficulties or, given her age, to be thrust into menopause. She found out she was wrong on both counts.

"After the surgery, sex was the last thing on my mind," Bartholomeus says. "I fell apart every time I looked in the mirror. So my husband and I put things on hold. We figured that when the chemo ended, things would come back normally. But we found out that because of the 'chemopause,' I had extreme dryness, vaginal atrophy and a great deal of pain."

Bartholomeus' symptoms are a result of the damaging effect—possibly permanent—of the chemotherapy drugs on her ovaries. In women who have undergone chemotherapy, biopsies often reveal ovaries that resemble those of elderly women. The ovaries are the primary source of both estrogen and testosterone. Without estrogen, the swelling and lubrication of the vagina that normally occurs with sexual arousal is lost; the mucous membranes become dry and thin, and the vagina may shrink, resulting in pain when intercourse is attempted. Testosterone in women, as in men, stimulates sexual desire, and also affects the level of pleasure that a woman feels. Kaplan reported that women with low or zero levels of testosterone (as measured by blood tests) found it difficult or impossible to have orgasms, with a partner or by themselves.

Surprisingly, according to Jeanne A. Petrek, MD, a breast surgeon at Memorial Sloan-Kettering Cancer Center in New York City, "we don't really know why the ovaries get destroyed by chemotherapy." Chemotherapy drugs attack rapidly dividing cells, but the ovaries, which have their lifetime supply of eggs from a woman's birth, are not rapidly dividing, Dr. Petrek says.

Whether a chemically induced menopause will be permanent, she adds, depends in large part on the age of the woman. "The closer you are to the age of natural menopause, the more likely it will be permanent," she says. Young women may lose their periods for up to two years before their ovaries begin to function again.

While the mechanism of chemotherapy's effects on the ovaries is not well-understood, Petrek says, studies have shown that some kinds of chemotherapy drugs are more damaging to these organs than others. The so-called alkylating agents like Cytosan affect the ovaries more than drugs like Adriamycin, which, ironically, causes more hair loss than Cytosan. The effects of newer drugs such as Taxol are completely unknown. Drug manufacturers do not provide information about the effects of anticancer drugs on ovarian functioning.

One study suggests that tamoxifen treatment is more sparing of sexuality than chemotherapy. A 1996 article in *Cancer Nursing* by oncology nurse Stacey Young-McCaughan reported that women who received chemotherapy were three times more likely to report decreased libido, 5.5 times more likely to report vaginal pain and 7.1 times more likely to report difficulty achieving orgasm than women treated with tamoxifen. The study involved 67 women who had been diagnosed, on average, seven years previously.

Petrek is now doing research funded by the Department of Defense to determine which of the various drugs and drug combinations are most toxic to the ovaries and to fertility. The study, limited to premenopausal women up to age 45, will also assess the drugs' impact on their sex lives.

## LIKE AN 80-YEAR-OLD WOMAN

While Kaplan was pleading for attention to the effects of chemotherapy on sexuality, the breast cancer community was focused on minimizing the damage of breast cancer surgery to a woman's body and self-image. As a result, women these days often have the option of a lumpectomy instead of a mastectomy, and may choose from a range of breast reconstruction techniques.

As important as these options have been to some women's self-image and comfort, they may have missed the sexual mark. In a 1994 monograph in the *Journal of the National Cancer Institute*, psychologist Leslie Schover concluded that regardless of whether a woman had undergone a radical mastectomy, immediate or delayed reconstruction, or breast-conserving surgery, she ended up equally satisfied—or dissatisfied—with her sex life, and equally well-adjusted psychologically.

"Research on quality of life after treatment for breast cancer has been guided by stereotypes," Dr. Schover wrote. "The traditional view...was of a middle-aged or elderly homemaker whose main concern was losing her breast."

After her diagnosis in May 1996, Julie Cole had both her breasts removed. But it was not the trauma of the surgery that impacted the quality of her sex life. Within a month of the start of chemotherapy, her periods disappeared. "For me, it's like my sexuality just kinda died," says Cole, 51, who works in the production department of a newspaper in Wakefield, Rhode Island. "I have no interest in sex, and I experienced vaginal thinning to the point of pain. When my gynecologist did a Pap smear, she said it was like an 80-year-old woman in there."

Neither the gynecologist nor any of Cole's other doctors offered her any remedies for her loss of libido or vaginal aging.

Apparently, her experience is not unusual. Of the 67 women surveyed for the 1996 *Cancer Nursing* article, 82 percent said they had never been asked by either their doctor or a nurse about sexual issues. In fact, interviews with survivors show that they take the initiative, bringing to the attention of their doctors remedies they've learned about on the Internet, or on television programs such as *The Oprah Winfrey Show*.

One remedy they discuss is the Estring, a device impregnated with estradiol, the human form of estrogen, which is inserted into the vagina and left there for three months. Unlike other forms of estrogen replacement therapy, the Estring has been shown in tests to temporarily raise the blood levels of the hormone only a small amount, while restoring lubrication of the vaginal tissues. It could, therefore, be a breakthrough treatment for survivors for whom the use of oral or cream conjugated estrogen supplements (which come from the urine of pregnant mares) is considered too risky.

The Estring's manufacturer, Pharmacia & Upjohn, has obtained FDA approval for use of the drug in postmenopausal women, but not in breast cancer survivors. According to Henk de Koning Gans, MD, Upjohn's vice president for product development for women's health and urology, to prove the Estring's safety for survivors would require a 10-year follow-up study involving between 10,000 and 20,000 women—"an enormous and very expensive task," he says. The company has no

continued from page 50

lubrication was restored, and most of the women found the product comfortable and easy to use.

Measurements of changes in blood levels of estradiol in these women showed only small, temporary increases, indicating that the Estring may be safe for breast cancer survivors. Jeanne A. Petrek, MD, a breast surgeon at Memorial Sloan-Kettering Cancer Center in New York City, describes the temporary rise in blood levels as "insignificant." However, because the Estring has not been tested in breast cancer survivors, Dr. de Koning Gans says, the *Physicians' Desk Reference* warns against this use.

Other remedies include regular use of lubricants and vaginal dilators. The dilators allow a woman to find out for herself "whether penetration will be comfortable before she's in a sexual situation," says Sarah S. Auchincloss, a New York City cancer psychiatrist.

### LOSS OF DESIRE AND SENSATION LESS PLEASURABLE ORGASMS

Breast cancer survivors who lose desire for all types of sexual activities, including masturbation, may be suffering from a deficiency of the hormone testosterone, also produced in the ovaries of healthy women. Loss of sensation in the nipples and clitoris, as well as fleeting, barely pleasant orgasms, are other symptoms of this deficiency.

Although pharmaceutical companies make combination estrogen-testosterone products, none of them offers a testosterone-only version. Therefore, women who obtain a prescription for testosterone must have it made to order by a compounding pharmacist. (See Resources on page 79 to locate compounding pharmacists.)

Pharmacist George Roentsch dispenses testosterone in a cream that can be rubbed on to the vulva, inner thigh, wrist or abdomen. It costs approximately \$45 a month. Because the dosage is small, no more than 1.5 milligrams a day, he says, masculinizing effects, like facial hair growth, are rare.

On the question of safety for breast cancer survivors, the studies aren't there, says Barbara Bartlik, MD, a New York City psychiatrist and sex therapist who still prescribes testosterone for her patients in consultation with their oncologists. Even when used as a cream, she says, about one percent to two percent of the testosterone can be converted by the body into estradiol.

To help with desire and arousal, women can also try the new generation of erotic videos produced and marketed by women, as well as erotic books and sex toys. (See Resources.) Airing one's feelings in support groups, or with the help of a sex therapist experienced with cancer survivors, can also help eliminate feelings that block the way to sexual pleasure.

plans to do so. "As a company, you have to make a decision about whether you want to follow a control group for 10 to 15 years, which is extremely expensive for a product that would never be a big money generator," he adds.

Knowledge about and availability of testosterone products is even more limited than estrogen products. While combination estrogen-testosterone products exist, no pharmaceutical company makes a testosterone-only product for women because "they can't patent it," says pharmacist George Roentsch. His company, The Apothecary, in Keene, New Hampshire, fills between 30 and 50 prescriptions a day for testosterone cream that is compounded to order and mailed to women all over the country.

Definitive research on the efficacy and safety of testosterone supplementation for cancer survivors has yet to be done. Kaplan's work does not prove that testosterone replacement therapy restores libido, Schover says, because Kaplan was also the sex therapist of the patients she studied, and there was no control group to eliminate a resultant placebo effect. "I keep looking for double-blind studies of testosterone, and I haven't found any that satisfy me," Schover says. "It is very difficult to get funding to study hormonal treatments for breast cancer patients. Some trials are going on for estrogen replacement therapy, but it has taken a lot of political clout to get those funded."

Barbara Bartlik, MD, a New York City psychiatrist who worked with Kaplan, is convinced that nothing but testosterone will restore sexual functioning in women who have a deficiency. A diagnosis of deficiency, she says, is based on a range of symptoms indicating a global loss of sexual functioning, both with a partner and during masturbation, and a history that includes a physical event, such as chemotherapy. In such women, she confirms Kaplan's finding that with replacement therapy, "it's a night-and-day difference."

### WORKING THINGS OUT TOGETHER

Adjusting to the sexual aftermath of breast cancer treatments can be very difficult in the absence of good communication and good information. For the present, survivors will have to rely primarily on self-help to work things out, according to Sarah S. Auchincloss, MD, a New York City psychiatrist affiliated with both Memorial Sloan-Kettering Cancer Center and Columbia Presbyterian Hospital.

"Women should not wait for the professional communities to get themselves up to speed on relationship and sexuality issues," she says. "We don't have the research, the products, the professionals, but women can do a lot for themselves. Women have to say, 'it's OK for me to want sex back in my life.' But you may have to do a lot of the work yourself."

Thanks to the Internet and to growing interest in the subject among support groups and activists, it is becoming easier to reach out for help.

Bruni Cofresi-Toroi and her partner, Olga Alvarado, did just fine through all the chemotherapy and radiation treatments that followed Cofresi's diagnosis in June 1997. But when she started on tamoxifen, there was trouble. "My *continued on page 72*

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## THE SECRETS ABOUT SEX

*continued from page 52* partner didn't know how to take it when she was kissing me and it was all dry," says Cofresi, a 40-year-old police officer from Alexandria, Virginia.

They decided to attend a workshop at the Mautner Project for Lesbians with Cancer, a support organization. The group discussed the use of lubricants, which the couple had not tried, and one member "ordered gel for us as a present," recalls Cofresi. "It is terrific."

Henrik Petersen runs a support group for male partners of breast cancer survivors in New York City, and sometimes the talk turns to sex. The group is rarely larger than five or six men, very small, he says, compared to the potential number. "The men talk about the awkwardness of re-establishing the sexual relationship with their wives," says Petersen. "And they talk about their fear, because they are reconnecting in a way that has been abruptly terminated for four to six months or longer. They are afraid of hurting their wives. They're not sure how to approach talking about it, or initiating sex."

In the absence of opportunities to discuss their feelings, men can harbor misconceptions that can be deadly to their relationships. "Women I talk to say they lost their husbands after they got cancer," says Bettye Green, founder of Women in Touch, a support group that reaches out to black women with cancer. "Some of the men think it's contagious, or that she's not a full woman anymore."

Several of the survivors interviewed for this article thought their suffering was unique until they turned on their computers and found others on the Internet who shared their pain. This has not only been comforting—it has made them determined that other women get the help they need. "Anything my own experience can do to help anyone else, let's get it out there," Julie Cole said in explaining why she was willing to discuss intimate details of her sex life. "I know so many women are suffering, and so many men. There has to be a better way, there really does." ■

# M Companion

## IDEAS AND RESOURCES FOR RECOVERY

### PREMATURE MENOPAUSE

*A debilitating side effect is finally studied*

BY CARLY BERWICK

Until the last decade, menopause had barely been studied by the research and medical community. So it's not surprising that premature menopause has likewise been an unheralded, but fairly widespread, phenomenon, affecting nearly 250,000 women in the United States. Premature menopause, also called premature ovarian failure, has many causes. For some women, their period just disappears one day for no apparent reason. But others know exactly what caused their menses to stop: chemotherapy.

Women who undergo chemotherapy are usually warned by their doctors that early loss of menses is a very common side effect, especially with aggressive regimens. Menopause is typically called "premature" when the period stops for more than three to six months before the age of 40, though there's still debate over the cutoff age (sometimes 44 is used, sometimes 50).

Some survivors with early menopause have, in fact, had their periods return. Almost always, loss of menses is accompanied by the usual symptoms of menopause—hot flashes, lowered estrogen levels, mood swings and insomnia. And while premature menopause is known to be a side effect of chemotherapy, not much is known yet about which regimens are most likely to induce it, or whether it has secondary health effects, such as increased risk of osteoporosis or heart disease.

As public discussion of menopause becomes increasingly acceptable, chemotherapy-induced premature menopause—which can also be called chemotherapy-related amenorrhea (CRA)—is finally getting its due. In the summer of 1997, Memorial Sloan-Kettering Cancer Center (MSKCC), in conjunction with the Wake Forest University School of Medicine,

launched the first-ever prospective study of breast cancer's effects on premature menopause and quality of life. The study, which has to date signed up 300 women to answer detailed questionnaires, will track such factors as sexuality, sleep disturbances, hot flashes and subsequent pregnancy.

One previous study, published in 1996 in the *Journal of Clinical Oncology*, reviewed all existing literature on premature menopause in women treated for breast cancer with chemotherapy, and confirmed that the three key variables determining risk of CRA are age, chemotherapy regime and cumulative dose. In general, younger women have a reduced risk, probably because their ovaries have not yet approached what seems to be a biologically "programmed" set point for ovarian cell death. For women under 40 who went through CMF (cyclophosphamide, methotrexate and fluorouracil), the authors found the incidence of premature menopause to be 40 percent, while for women over 40 it was 76 percent.

Martha Haley, a staffer at the Y-Me National Breast Cancer Hotline, was a 36-year-old mother of three when she was diagnosed with breast cancer. After the fourth round of chemotherapy, her period stopped. "The hot flashes were unbearable," Haley says. After 10 months of being amenorrheic, she began menstruating again. But then, four months ago, she entered "natural menopause." Haley is only 39 now. She, like other survivors who have had temporary amenorrhea, probably went into menopause much earlier than she might have "naturally."

Because of the risk of cancer recurrence additional estrogen poses, many breast cancer survivors cannot use hormone replacement therapy to ease *continued on page 76*

continued from page 75 menopausal symptoms and combat bone density loss. Some health practitioners and doctors advocate soy products as an alternative, but others caution that since not much is known about how soy works, there's a risk that soy acts like estrogen.

Jeanne Petrek, MD, a breast surgeon at MSKCC and a lead researcher on the prospective study, says that they are keeping careful track of how women are coping with premature menopause and its often debilitating symptoms. "People are taking all kinds of things because they're miserable: ginkgo, soy, herbal remedies."

Ultimately, Dr. Petrek believes her study will allow different chemotherapy regimens to be better evaluated and weighed by

patients and doctors, who will take into account the regimens' relative effects on premature menopause. Existing data indicates that cytotoxins and alkylating chemicals are most associated with high rates of premature menopause—adriamycin and other antimetabolites least. Nothing is really known yet about the effects of tamoxifen (Nolvadex).

In the end, Petrek sees the study addressing an overarching issue of concern: "How do women feel about premature menopause, and how do they get over it?" In response to an Oregon Menopause Network survey, one woman who experienced chemotherapy-induced menopause at the age of 36 wrote, "Although I was told chemotherapy would bring on early menopause, I was not at all prepared for the physical and emotional changes." □

## CLINICAL TRIALS

*Low-risk trials may advance knowledge of detection and treatment*

COMPILED BY HELEN SCHIFF AND CHRISTINE HARAN

There are very few clinical trials for women with early stage disease—and those that do exist often carry some risk. That's why MAMM has identified several important clinical trials that women with breast cancer can participate in with virtually no risk. Although they involve noninvasive procedures, these trials can help answer questions about the detection and treatment of breast cancer. Enrolling can help researchers uncover information that may be of benefit to you, as well as future generations.

STUDY	OBJECTIVE	ELIGIBILITY	WHAT'S INVOLVED	CONTACT
<b>CHRONOTHERAPY</b>	Multicenter study to determine if the timing of breast cancer surgery, with regard to menstrual cycle, is associated with five-year disease-free survival	For women with Stage I or II breast cancer; no previous neoadjuvant therapy	Hormone levels and menstrual history will be obtained within 24 hours of surgery; if surgery requires two procedures, both must occur within the same phase of the menstrual cycle	NCI: 800-4-Cancer; if you have questions, call Clive Grant, MD, North Central Cancer Treatment Group: 507-284-2644
<b>POSITRON EMISSION TOMOGRAPHY (PET) SCANS</b>	Study to examine the effectiveness of PET scans in detecting sites of breast cancer, the extent of local and distant spread, and to evaluate tumor response to chemotherapy	For women with Stage II, III, IV or recurrent breast cancer	PET scans will be given before, during and after chemotherapy; patients will receive an injection of fludeoxyglucose F18 in the breast and/or metastatic site	NCI: 800-4-Cancer; for info on PET scan studies around the country, call the NCI Clinical Studies Support Center: 888-624-1937
<b>MAGNETIC RESONANCE IMAGING (MRI)</b>	Multicenter study to determine the value of MRI in detecting breast tumors	Women with suspicious mammographic or clinical exams	Patients undergo MRI exam; tumors biopsied; one year of follow-up	NCI: 800-4-Cancer; Robin Holmes, University of Pennsylvania: 215-662-6081, holmes@oasis.rad.upenn.edu
<b>PREMATURE MENOPAUSE AND QUALITY OF LIFE</b>	Memorial Sloan-Kettering Cancer Center (MSKCC)/ Wake Forest University School of Medicine study to examine how breast cancer affects women's menstrual cycles and quality of life	Must be between the ages of 18 and 45; have been diagnosed with Stage I, II or III breast cancer within the last eight months; have had regular menstrual cycles at the time of diagnosis	Initial questionnaire sent to all participants, followed by an additional questionnaire every six months for three years; every woman will be provided with menstrual cycle diary to be filled out for the duration of the study	Joanna Winawer, MSKCC: toll-free at 877-636-7562 or winawerj@mskcc.org

## Special Women's Health Series: Part I

Julie Brier's  
blind faith in  
her physician  
cost her  
a breast and  
scarred her  
for life.

She wants you  
to learn from  
her story.

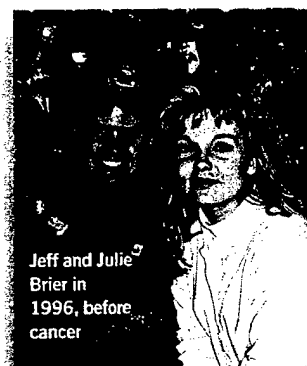
I got  
breast cancer  
at  
24





## AN EXCLUSIVE GLAMOUR INVESTIGATION INTO HOW DOCTORS COULD MISS YOUR BREAST CANCER — JUST BECAUSE YOU'RE YOUNG.

By Liz Brody



Jeff and Julie Brier in 1996, before cancer

**t**hank God that lump was nothing, Julie Brier thought as she got dressed after the doctor's exam. The 24-year-old Indiana woman had been very uneasy ever since her husband, Jeffrey, found what felt like a pebble in her right breast while the two of them were snuggling in bed one night. She'd wanted to have it checked out immediately but they had just moved and she didn't have a regular doctor.

Fortunately, she tracked one down who could see her 11 days later. That doctor seemed like a nice enough man, she recalls, and told her not to worry: Women her age often had lumpy breasts, and it was probably just a cyst. Her medical chart from that visit shows his diagnosis: "fibrocystic disease" (overall breast lumpiness that changes during your menstrual cycle) and a recommendation to "stop caffeine, chocolate, reexamine in six months." It was August 1, 1997; the receptionist made a return appointment for March 6, seven months later.

Julie and Jeff, an electrical engineer who was 26 at the time, hightailed it from the office that day feeling utterly relieved. "The doctor went out of his way to reassure us that it was absolutely nothing," remembers Julie, a petite blue-eyed blond who had thick, wavy hair halfway down her back and a tomboy streak she regularly indulges by going four-wheeling in her off-road vehicle across the Indiana fields. This was not the time to be sick, she recalls thinking; she and Jeff had been moving around the country since marrying three years earlier, but now, finally, they had settled down outside of Indianapolis, near her parents' home, and were planning to find steady work and start a family.

That fall and winter, Julie tried to put the lump out of her mind as she interviewed for various jobs—at a hospital, bank, children's publishing company—and worked on getting pregnant. But she noticed that the lump never vanished, and in February, her breast started to ache. One night it hurt so badly she took painkillers and went straight to bed. So a month shy of her return appointment, she called her doctor. No problem, he said; he'd drain the lump—a procedure often used for a persistent benign cyst. But the next day when he injected her mass with a needle—twice—it became clear that he couldn't siphon out any of the fluid that cysts are usually filled with; the little fluid that did come out was bloody. "He

still convinced me it was nothing, but recommended that I see a breast specialist," Julie recalls. "I did, and when that doctor examined me 10 days later, on February 20, he said, 'I want it out.' I was annoyed that I had to deal with surgery. I still was thinking that it was a cyst."

She found out how wrong she was on March 6, when the surgeon called with the biopsy results. Julie was home alone, sitting at the dining room table when she picked up the phone. "Did he just say cancer to me?" Julie remembers thinking, her mind stuck on reverberations—*cancer, cancer, cancer*. "Is he telling me now that my cyst could kill me? How could I possibly have breast cancer? I'm only 25!" She hung up the phone and sat staring at the flowers on the wallpaper: Was the cancer just in her breast, she wondered? Was it just one lump, or could her whole body be riddled with this deadly disease? She burst into tears, too shocked with terror to move. →

### You found a lump, Now What?

Breast cancer is extremely rare in young women, but it does happen. That's why it's critical to do monthly self-exams and push your doctor to investigate suspicious lumps—including ones in your armpits and above your bra line. "Any new lump needs to be explained," says radiologist Phyllis J. Kornguth, Ph.D. and M.D., an associate professor at Duke University Medical Center in Durham, North Carolina. If you do find a breast lump, here's a step-by-step take-charge plan:

- **Wait until a week after your period, then check your breast again.** Many women have lumpy (often called fibrocystic) breasts, especially right before their menstrual cycles. If the lump disappears, you can quit worrying.
- **If the lump is still there, schedule a breast exam right away.** While most cancerous tumors are extremely hard and painless, benign lumps tend to be rubbery and mobile and may be tender to the touch. Even if your doctor thinks your lump is benign, she at least should tell you to return in a month or two. If you don't want to wait, you can insist it be tested then or get a second opinion.
- **If the lump doesn't disappear or seems suspicious at your next checkup, the next step may be a mammogram, ultrasound or both.** A new study shows that, for dense breasts (common under age 35), the two technologies combined are almost twice as effective at detecting tumors as mammography alone.
- **Even when your tests are negative, if the lump doesn't go away in another month, see a breast specialist for a fine-needle aspiration (a thin needle is used to remove cells for further testing) or a biopsy.** The biopsy is the only definitive way to determine whether a lump is benign or cancerous. You can have either a surgical biopsy or a less invasive large-core needle biopsy. If any doctor ever says you're too young for breast cancer, find another one ASAP.

—MARY DIXON



## Doctors' Deadly Mistakes

Could Julie Brier's nightmare happen to you? According to an exclusive *Glamour* investigation, it could. The shocking truth: All too often doctors fail to catch breast cancer in young women, reasoning that this lethal disease just doesn't affect those under 35. They're usually right—but sometimes they're dead wrong.

In interviews with more than 25 breast cancer survivors who were afflicted in their twenties and early thirties, *Glamour* repeatedly heard the same story of young patients being dismissed from the examining room with a friendly pat on the shoulder, their tumors chalked up to common fibrocystic breast disease or benign masses called fibroadenomas. Some doctors failed to even examine women they believed were too young to be diseased. It's almost as if there were a script being passed around: "My gynecologist said, 'You're too young, it's not cancer.' She told me to stop eating chocolate and cut out all caffeine," says a 33-year-old from San Diego who was diagnosed two months later with aggressive cancer that required her to have a mastectomy. "My doctor said, 'Don't worry, you're only 22. You don't have breast cancer,'" says a 27-year-old from Chicago, who later discovered she had, in fact, an advanced stage of the disease: a nine-centimeter tumor and 10 lymph nodes filled with cancerous cells.

Several studies back up the frightening fact that young women suffer damaging lags in having their breast cancer detected—the most recent being a review of more than 5,000 patients in the United States and elsewhere published last April in the British medical journal *The Lancet*. "When you're young with a breast lump, a typical doctor's response is, 'Come back and see me in six months,'" says activist Ellen Stovall, a member of the National Cancer Policy Board (NCPB) at the Institute of Medicine, which recently issued an alarming report highlighting the fact that there are no mandated national guidelines doctors can or must follow in dealing with breast cancer in younger women.

But six months is far too long to wait, warn many experts. For any breast cancer patient, even a three-month delay in treatment could make the difference between being alive and dead at the end of five years, new research published in the same issue of *The Lancet* shows. And if you're young, the deadly cells may multiply even faster: The average time it takes a breast tumor to double in size for women of all ages is about 90 to 100 days, but in your twenties or thirties, the average is 50 to 60 days. In addition, the types of breast cancers young women get are often more aggressive—meaning they spread faster and are likelier to kill a patient within five years—than those that strike women over 35, according to a review by the National Cancer Data Base, which collects data from hospitals. "As a doctor you have got to catch these [young] patients at the outset, because you only have one shot at it—



**Jeff was outraged that Julie's cancer wasn't caught sooner. "The thought that I could lose her now... I just couldn't take it," he says.**

deserves to slip through the cracks. "That any physician would dismiss even a single breast lump as anything but serious is totally unacceptable. I don't care if the person is 12 or 112," concludes Stovall, who is also executive director of the National Coalition of Cancer Survivorship and a cancer survivor herself. "We're not talking about biopsying every breast lump; we're talking about listening to young women. Cancer may be very, very unlikely, but it needs to be ruled out."

## A Dangerous Delay for Julie

Despite the lack of hard-and-fast guidelines, most cancer organizations and many breast experts do agree about how a doctor should proceed if you walk in with a breast lump: At minimum, she should recheck it in a month or two, one to two weeks after your period. Then, if it's still there, she should evaluate it immediately through one or more diagnostic technologies (see sidebar, page 183).

"Any breast lump that doesn't [go away] within one menstrual cycle should be evaluated for potential biopsy," insists Jo Anne Zujewski, M.D., senior medical oncologist at the National Cancer Institute. "And I tell doctors to make sure that the patient has the appointment before she walks out the door—it's not, 'Call me back.'"

Waiting beyond one cycle is dangerous, confirms Patrick Borgen, M.D., chief of breast service at Memorial Sloan-Kettering Cancer Center in New York City. "With the technology that we have, the doctor should be able to prove to you what your lump is. There is almost no excuse in this day and age to use guesswork. 'Come back in three months?' Well, gee, if it's cancer, you've wasted 12 weeks!"

and if you botch it at the front end, it's very hard to recover from that mistake," says Joseph Simone, M.D., coauthor of the NCPB report and medical director of the Huntsman Cancer Institute in Salt Lake City. "Whoever the doctor is at the beginning can have a profound influence on the outcome of the patient."

Abigail Lavine would agree—if she could. The New York City woman died two years ago from breast cancer at age 33. But before she did, she filed suit against her doctors, alleging they delayed tests and referrals so long—a year and a half after she first complained of a lump—there was no recovering: Her cancer had spread to her spine, liver, lungs and possibly brain. Her doctors deny her allegations.

Health-care policymakers are quick to point out that M.D.s may shrug off young women's breast lumps because the vast majority are benign: Your chances of contracting breast cancer by age 35 are just one in 622 versus one in 50 by the age of 50. Even the heads of several major breast cancer organizations candidly told *Glamour* that because of those low rates, they have bigger battles to fight than young women's treatment by physicians. But the bottom line is this: No woman

Julie Brier wasted more than twice that much—and it cost her precious time in the fight to save her life. Over the six months she spent dutifully cutting back on her daily Coke intake, the mass she thought was a harmless cyst was actually more than quintupling in size—growing from the equivalent of a pencil eraser (0.5 by one centimeter, as her doctor had noted in her chart when she first went in) to the size of a chicken egg. Nineteen days after she got the biopsy results over the phone, she was in the hospital having her entire right breast removed. When the surgeon opened her up, he also found that the cancer had metastasized, or spread, to a lymph node, an immediate sign that Julie's disease was more likely to recur. "It was pretty serious," says T. Howard Lee, M.D., the oncologist at St. Vincent's Hospital in Indianapolis who took over her care after her mastectomy. "She had a sizable tumor—five by four by five centimeters—and the fact that she had metastasis in the lymph node was worrisome." He immediately prescribed six months of intense chemotherapy, 28 days of radiation and five years on tamoxifen, the antiestrogen drug newly approved for breast cancer prevention—therapy he describes as "aggressive treatment."

Could Julie have been spared some of this agony if her doctor had followed up sooner after she first showed him the mass? Medical experts say yes. Treated then, it's likely that she could have had a simple lumpectomy and kept her breast, according to one of the cancer specialists who recently reviewed Julie's case. In fact, the odds of the cancer coming back within five years would have been only 8 to 13 percent compared to what it is now—a whopping 50 to 64 percent—thanks to the growth of the tumor, the expert speculates. He adds that the delay of treatment also most certainly allowed the cancer to spread to her lymph node, upping her odds of dying within the next 10 years to as much as 63 percent.

"Why couldn't he have just sent her for a mammogram at the beginning?" asks her mother, Patty Southard. "What was it to him? I know breast cancer is not that common when you're under 30, but my God, these girls are dying."

## A Righteous Rage

In August 1998, one year after Julie found her lump, she sat hooked up to a chemotherapy IV at the infusion clinic, her right breast removed and a new one reconstructed with a saline implant padded with muscles from her back. Long jagged scars ran like barbed wire between her shoulder and butt and across her bust.

Chemo is grueling: Every time you go in, you're slapped with three hours of clear liquid toxins dripping slowly from the bag, silently stealing your hair, endangering your fertility, inducing days of nausea. Julie's particular chemo cocktail included Adriamycin, known among patients as the Red Devil, a fruit-punch pink poison so potent it can literally burn the flesh around a vein. For six months, while Julie was going for her chemo sessions, her body smelled like chemicals—the odor coming through her pores so strongly it often made her gag. She gained 20 pounds from the steroid medication used to quell the vomiting. And the blond locks she'd been so proud of fell out

in clumps. "The night I shaved her head, what was left of her hair, that was bad," recalls Jeff. "It really hit me. It wasn't fair. She's so young."

Julie and Jeff had been only 15 and 17 when they went on their first date. He'd been devastated at her diagnosis, holding her hand through every doctor's appointment, every test, every treatment. "The thought that I could lose her now..." he says. "I just couldn't take it. She is the single most important thing in my life. We always pictured ourselves sitting in rocking chairs growing old together. It was just too soon for her to be taken away from me. Too soon."

Julie felt the same way, and as the chemo continued, she thought back to how her gynecologist had dismissed her. "He called and left a message after he found out [about my cancer diagnosis] saying that he was sorry, that at the time he didn't have any reason to believe it was anything but a cyst," Julie remembers. He seemed genuinely concerned, she thought, but so what? It was too late. "I was really angry that he hadn't taken my lump seriously, and I was afraid he would do it to another girl," she says. In the midst of chemotherapy, sick as a dog, Julie decided to sue. Between hospital visits, she cleaned herself up, tugged a blond wig over her bald head and marched into the law offices of Vernon J. Petri in downtown Indianapolis. She wanted to make a difference.

Breast cancer is actually the number-one condition for which patients file medical malpractice claims, ac- (continued on page 206)

## She saved her own life

CATCHING A LUMP EARLY MADE ALL THE DIFFERENCE FOR SHARON EPPES, NOW A 34-YEAR-OLD LAWYER IN WILMINGTON, DELAWARE.



"I found a lump during a breast self-exam when I was 25, and I pushed to have it tested. When my surgeon told me I had breast cancer, my first thought was, I am going to die. But the doctor went on to say that because we caught it very early I could treat it with a lumpectomy and radiation. Though I was petrified, I was relieved that I didn't have to lose my breast and have chemo. The next few weeks, I was in a daze. I had my surgery and two weeks later got married. I remember walking around the church thinking, This should be the happiest time of my life and instead I have this big black cloud over me. The day after I got back from my honeymoon in Bermuda, I started six weeks of radiation.

"It's been nine years since I was first diagnosed, and I'm doing really well. I have two healthy daughters whom I breast-fed, a successful career as a lawyer and a 95 percent

chance of surviving this disease, according to my doctor.

"I know that catching the lump early definitely saved my life. Two years ago when I found a lump in my other breast, I went straight to the surgeon to have the mass removed. It turned out to be a precancerous tumor that hadn't spread at all, but most likely would have if I'd left it alone.

"Because of my experiences, I've been speaking to high school girls about the importance of breast self-exams through an American Cancer Society volunteer program. Some don't want to check themselves because they think they are too young or are afraid of actually finding something. But I tell them, 'You want to deal with it. Then you can have a story like mine, where I had to go through minimal surgery, didn't lose my hair, never really got sick, and was able to go ahead and live my life.'"

—DINA ROTH

COMING IN AUGUST: Part II of *Glamour's* Special Women's Health Series

cording to Physician Insurers Association of America (PIAA), and many of the plaintiffs are young. For most of these women, "doctors said their lumps were nothing or fibrocystic disease," explains Lori Bartholomew, a coauthor on the PIAA's most recent breast cancer study. And those doctors are paying: Kathy Ball, of Warwick, New York, for example, who was diagnosed with breast cancer at age 34, was awarded over a million dollars, having sued her doctor for failing to examine her breast after she came in with a suddenly inverted nipple (he claims she never informed him of the problem). By the time she was diagnosed a year later, in 1992, her cancer was so advanced she was given only one or two years to live. "I am one of the lucky ones," she says, still hanging in today. Six other women in the New York area alone won up to two million dollars each for such experiences in the last six years, according to the *New York Jury Verdict Reporter*.

Back in Indiana, as Julie's case built momentum, her doctor explained through his lawyer why he treated Julie the way he did. "A possibility always exists that a lump may be cancerous," he stated. "However, given the plaintiff's age, the fact that the lump was shrinking, and the plaintiff's negative family history of breast cancer, the possibility that the lump was cancerous was remote."

While this explanation sounds reasonable enough, it should not have reassured the doctor enough to send Julie away for six months. For one thing, while Julie didn't have any family history of breast cancer, neither do 70 to 80 percent of all breast cancer patients, according to experts. In what became the heart of the case, lawyer Petri got gynecological and oncological experts to state that dismissing the possibility of Julie's having cancer—remote as it was—violated an acceptable standard of care and caused her serious bodily harm. "It is my opinion that earlier diagnosis and treatment of her cancer would have provided this patient with a much improved prognosis for survival," wrote one. (Julie's doctor declined to speak with *Glamour*.)

"The doctor was so nice—that was the hardest part of suing," says Julie. "But I'd be sitting in the bathtub, looking down at my scars and thinking, This is awful, I can't believe I'm going through this," she says. "I just don't feel like he took my case seriously enough to do the necessary tests. We could have saved a lot of time, a lot of heartache, a lot of surgery, and saved me from the fact that I have to live the rest of my life in fear that my cancer will come back. That's what really upsets me—that during those six months the cancer made its way out of my breast and into my lymph node, increasing

the chances of a recurrence. When I think about that, I feel completely justified."

## In a Doctor's Defense

It goes without saying that the doctors who fail to diagnose breast cancer in young women are not evil characters out to ruin female lives. Many blame breast cancer's low incidence among the young. But how unlikely is it? While the odds of getting it by age 25 are only one in 19,608, by age 30, your risk leaps to one in 2,525, and by 35, one in 622. Even for the age groups with the least risk, every day in 1999 approximately two women under 30 will get diagnosed with the disease in the United States, according to the American Cancer Society.

Two women a day is a lot in terms of human tragedy, but spread across the entire country, it means doctors simply don't have hands-on experience with detecting cancer in young breasts—and it's with experience more than textbook reading that doctors learn their craft. Brenda Solorzano, a 30-year-old policy analyst at the California Medical Association, knows this all too well. As she sits in her offices overlooking San Francisco Bay typing, several nail-less finger nubs betray her identity as a veteran of chemo, which works by killing fast-growing cells, sometimes affecting nails as well as hair. They are reminders of the breast cancer that her primary care physician, Marci Gottlieb, M.D., initially missed, assuming at first that the pain under her arm was a pulled muscle. "I just bought myself a car. I was saving up for a house, but I don't know if I'm going to be around that long. I want to live now," says Brenda, still recovering from a mastectomy, two courses of chemotherapy and radiation.

"Something like this makes you realize how carefully you have to listen to patients," says Dr. Gottlieb, who admits that she didn't think breast cancer at first in part because it's unusual to see the disease in anyone as young as Brenda. "If someone has strange pain in the chest area, you should just go ahead and do a breast exam, even when you think it might be unnecessary. And if a patient keeps complaining, it's important that you do every diagnostic test along the way."

Doctors' lack of awareness isn't the only problem for young women. There's also managed care. In all areas of medicine, attempts by managed care companies to keep costs down have raised questions about whether patients are getting the tests and attention they need. For one thing, many HMOs give participating physicians bonuses for limiting referrals to specialists. In a recent study of 766 California primary care physicians, over half felt pressure from their managed care organization to limit

such referrals—and worse, 17 percent felt that such pressure actually compromised their ability to give their patients good care. "The basic concept is that if doctors cost the health plan less—ordering fewer referrals to specialists, hospital services and laboratory tests—then at the end of the year they get some money back," explains Kevin Grumbach, M.D., one of the authors of the California study, which was published in *The New England Journal of Medicine*. "Typically, we found that the amount they get back is only \$5,000 to \$10,000. But we also found a few cases where physicians could earn as much as \$30,000 to \$40,000 a year by not referring patients."

If doctors are rewarded for limiting referrals and tests, the first breast cancer tests to go may be those considered least vital—in other words, those for young women who statistics imply are probably healthy. One Simi Valley, California, man claims that HMO economics prevented his 29-year-old wife from getting a desperately needed mammogram—to the point where, by the time she was finally diagnosed with breast cancer, it was so advanced that it killed her at age 34.

## Scarred for Life

Julie Brier finished her last radiation treatment on December 28, 1998, a few weeks after her 26th birthday. For the next five years she will take tamoxifen, which has a grim list of side effects, including hot flashes, weight gain and an increased risk of uterine cancer. Though the drug has mostly been tested in older women, Julie's doctors are banking on the hope that it will also work for her.

Meanwhile, in May, both sides in Julie's lawsuit agreed to a settlement. "The only question is how much money she's eventually going to get," says Petri. (Under current Indiana law, the maximum amount she is entitled to for medical malpractice is \$750,000.) Her doctor, however, has denied any wrongdoing—in particular, refuting the idea that, given her symptoms and medical history, he had a duty to follow up with her within a month of her appointment, and claiming that his recommendation to see her again in six months was appropriate.

Julie hotly disagrees. No matter how much money she receives, she says, she'll never recapture her youth—the carefree confidence, that raw "I'm immortal" walk down the street she says she had at 24. She tries to make light of her right breast, stitched like a football and numb to the touch, quipping, "What use does a breast have? It's not like I write with it or anything." But her body's plumped up from the steroids she took during chemo—a notoriously stubborn kind of weight that won't easily come off—and in

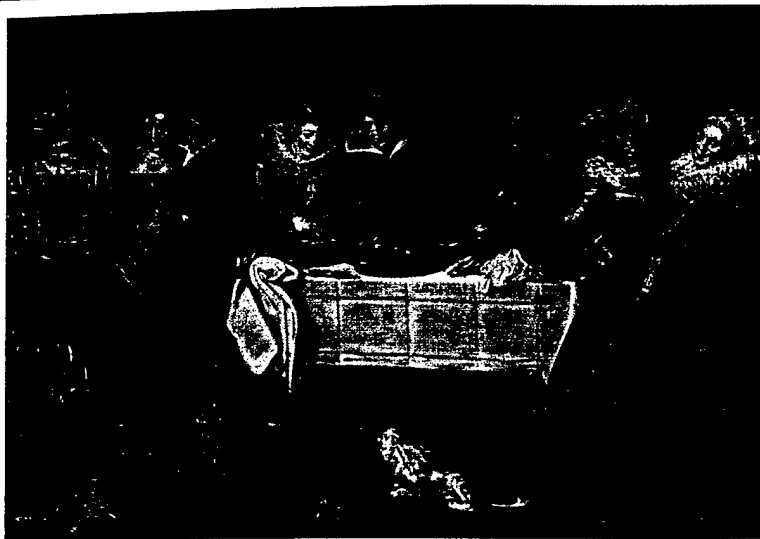
one of the mysteries of chemo, her once-blond hair is growing in dark and curly, a constant reminder that she is a changed person now. Hanging out in her parents' kitchen one day in April 1999, Julie cracks jokes and keeps everyone laughing as she fiddles with a necklace charm that dangles in the cleavage of her divided bosom: fake breast, real breast. The charm is a gold half heart that says "little sister" on it. Her older sibling, Vikki Reel, 28, is wearing the other "big sister" half. The two have always been thick as blood can get, reading each other's journals, finishing each other's sentences. And when Julie was diagnosed, Vikki packed up her two kids in Georgetown, Kentucky, and moved home for a month. "I felt so helpless," she says.

Julie herself can't imagine going through life without having children, but that's a tragic possibility. "When you get breast cancer chemo, your ovaries take a big hit and you're likely to go through menopause earlier than you would normally," says Jeanne Petrek, M.D., surgical director of the Evelyn Lauder Breast Center at Memorial Sloan-Kettering Cancer Center in New York City, who is currently studying which chemo drugs do the least fertility damage. (If you are under 45, have invasive breast cancer and wish to participate in the study, call toll-free, 877-636-7562.) The question is moot for Julie because tamoxifen has put her body in a state of mock menopause; she won't even know whether she can have children for five years.

"I don't feel like I'm as attractive as I used to be, and I'm always worried that Jeff's concerned about it—though he has never ever stopped telling me I'm beautiful," says Julie. In fact, she believes their relationship has become much stronger since her diagnosis. "The cancer has taught us an incredible lesson that I'm glad I learned as a young woman, rather than waiting until I was 60. We've figured out early on how precious life is and what's really important—and how not to take anything for granted."

Jeff wants to put her illness behind them, and so does Julie. Workouts, travel plans, maybe starting up a crafts business of her own—she tries to look ahead. And everyone around her marvels at her spirit. But at night in the shower, all by herself, she can't help but cry. "If by suing my doctor I can save just one other girl from this, it will all be worth it," she says. "Because I wake up taking tamoxifen, I go to bed taking tamoxifen. The thought of cancer is in my face all the time. And I'm wondering, What if there's one little cancer cell still hiding in my body? What if I get a recurrence? What if it comes back? I'm just so angry that here I am at 26 worrying about dying." ©

*Additional reporting by Maura Kelly.*



Dirck Hals, 1622. *A Merry Company*. From the collection of Dr. Gordon and Adele Gilbert of St. Petersburg, Florida.

*The diagnosis and treatment  
of breast cancer present  
unique considerations  
for women who are  
considering childbearing.*

## Pregnancy After Breast Cancer

*Mary L. Gemignani, MD, and Jeanne A. Petrek, MD*

**Background:** *The issue of pregnancy following the diagnosis and treatment of breast cancer is important because the incidence of breast cancer is increasing in women of childbearing age. The fact that many women are delaying childbearing, whether for educational, professional, or personal reasons, increases the number of women who will undergo breast cancer treatment before completing childbearing.*

**Methods:** *Data on pregnancy in breast cancer survivors are limited and consist only of retrospective data. This paper reviews the published literature on the influence of subsequent pregnancy on breast cancer, including three recent large-scale population-based studies.*

**Results:** *The survival of women with breast carcinoma who subsequently become pregnant is not reported to be decreased in any of the published series. However, several biases may be present that justify the concern regarding the conclusions.*

**Conclusions:** *Further research on the safety of subsequent pregnancy after breast carcinoma treatment is needed. To address these issues, patients are currently being accrued for a large, prospective, multicenter study of young breast carcinoma patients.*

### Introduction

The issue of safety following the treatment of breast cancer is of concern for the breast cancer survivor as well as for the physician involved in her care.

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*No significant relationship exists between the authors and the companies/organizations whose products or services may be referenced in this article.*

Because many women are delaying childbearing for different reasons (educational, professional, and personal), it is becoming increasingly more common for them to undergo breast cancer diagnosis and treatment before initiating or completing childbearing. The delay in childbearing to 30 to 40 years of age is concordant with an increasing incidence of breast cancer in those ages. Of the 178,700 new cases of breast cancer estimated for 1998, 10% to 20% will occur in women of childbearing age.<sup>1</sup> Physicians have stressed the complete rehabilitation of breast carcinoma patients, including reconstruction and psychosocial aspects. It is thus natural following the completion of therapy for the patient to inquire about pregnancy and childbearing.

The hormonal influence on mammary carcinogenesis is well known. The effects of first full-term pregnancy, age at menarche/menopause, and the use of postmenopausal hormone replacements are significant hormonal factors in the pathogenesis of breast cancer. In fact, the importance of the endogenous hormonal milieu on breast cancer promotion has been recognized for more than 100 years. In 1896, Beatson<sup>2</sup> noted the regression with oophorectomy in premenopausal patients with advanced local disease. The effects of estrogen on causing acceleration of the growth rate of micrometastases, stimulation of dormant micrometastases, or direct carcinogenesis of a new primary are of concern in patients with breast cancer. Few studies have addressed the effects of endogenous hormones in women who become pregnant after breast cancer treatment. Several retrospective studies have included only a limited number of patients, and population-based studies have only recently been published. A large, prospective, multicenter study that is currently ongoing will help to address some of these issues.

## Retrospective Series

The earlier literature stated that at least 7% of women who did not undergo oophorectomy underwent one or more pregnancies, and 70% of these pregnancies were to be expected in the first five years after cancer treatment.<sup>3</sup> Adjuvant cytotoxic chemotherapy depletes the number of fertile patients, but as many as 11% had a deliberate or unplanned pregnancy in a short-term chemotherapy study.<sup>4</sup> From the limited available literature, it has been generally observed that breast cancer patients who subsequently become pregnant have good survival rates, often the same or sometimes better than patients with no subsequent pregnancy.<sup>5,6</sup>

The limited data on outcome after subsequent pregnancy in breast carcinoma patients are derived from retrospective studies, some of which employ case-matching methodology in an attempt to eliminate the obvious bias of pregnancy occurring in those with the better prognosis.

Single institutions have conducted sporadic retrospective studies, each composed of fewer than 100 patients. In 1954, White<sup>7</sup> reported that eight (67%) of the patients who became pregnant lived at least five years and 58% survived 10 years. In 1962, a series of 52 patients from Memorial Hospital had an overall five-year survival rate of 52%.<sup>8</sup> Another similar-sized study reported in 1969<sup>9</sup> included 53 patients with five- and 10-year survival rates of 77% and 69%, respectively. In 1970, Cooper and Butterfield<sup>10</sup> reported a 75% five-year

survival rate in 32 patients, and 50% of patients in a 1973 series survived five years.<sup>11</sup>

Case-matching studies were also performed to lessen the influence of pregnancy occurring only in those with a good prognosis. In 1965, Peters and Meakin<sup>12</sup> matched 96 patients with subsequent pregnancy over several decades with patients with similar age and clinical stage. The patients with subsequent pregnancy had a longer disease-free and overall survival than those without subsequent pregnancy. In the 1970 Cooper and Butterfield analysis,<sup>10</sup> each of 40 patients who subsequently became pregnant were matched with two control subjects as determined by the clinical stage, age, status of lymph node involvement, and equal survival at least to the time of pregnancy. The patients with subsequent pregnancy had a survival time superior to that of the control subjects.

Memorial Sloan-Kettering Cancer Center reported an 80% five-year survival rate for stage I and II (AJCC classification) patients after subsequent pregnancy. The study included 41 patients collected over 30 years. No detrimental effect of subsequent pregnancy was noted, even among patients with positive axillary lymph nodes or among those whose pregnancy occurred less than two years following mastectomy.<sup>13</sup> In a 1986 nationwide French study,<sup>14</sup> the 10-year survival rate of 68 patients who had subsequent pregnancies was 71%. The survival of the negative-node patients was 90% at 10 years with no difference between cases and controls.

In 1989, Ariel and Kempner<sup>15</sup> found that subsequent pregnancies did not affect overall prognosis in a large private practice experience. The largest series<sup>16</sup> included 136 patients diagnosed over five decades at the Princess Margaret Hospital in Toronto and is an update of the series reported by Peters and Meakin in 1965.<sup>12</sup> They reported an excellent overall 5-year survival rate of 78%.

Data on subsequent pregnancy have also been reported in the analysis of adjuvant chemotherapy trials. Recurrence rates and survival for patients who underwent subsequent pregnancy were similar to those who did not.<sup>4</sup> A recent study from Athens was reported with 21 patients under the age of 35 years who had a pregnancy after treatment for breast cancer. The recurrence rate and survival of the 21 women was similar to patients of similar age and stage without pregnancy.<sup>17</sup>

Three groups of investigators in the recent reports have examined the question of the timing of the subsequent pregnancy on breast cancer prognosis. The effect of interval length between breast cancer diagnosis and

pregnancy affects prognosis because women who defer a pregnancy for many years are also those who have remained disease-free for greater period of time.

Clark and Chua<sup>16</sup> found that 72% of their patients became pregnant within two years of treatment. Those who became pregnant within six months had a comparatively poor prognosis — a 54% five-year survival rate compared to a 78% five-year survival rate among those who waited six months to two years to become pregnant after breast cancer diagnosis. Those who waited five years or more to become pregnant had 100% five-year survival from that point. They concluded that a wait of at least six months from completion of treatment is recommended. The data are consistent with the fact that the longer survival after diagnosis is, *per se*, an indicator of the patients' better prognosis (whether pregnancy occurs or not). The recent French series<sup>14</sup> and the Memorial Hospital series,<sup>13</sup> which are smaller in number, do not find a statistically significant difference between outcome of patients based on the interval.

How much reliance can be placed on these reports to allow us to adequately advise patients on subsequent pregnancy after breast cancer treatment? Since pregnancy is not coded as a disease or coded in any other way by the record room or tumor registry, cases over the previous decades are all found by memory, as is the situation with the Memorial Hospital series.<sup>13</sup> Even if a chart or tumor registry review of all premenopausal women had been undertaken, the occurrence of subsequent pregnancy may not be noted.

The Methods section of all of the retrospective series ignores the question of the denominator, the total number of patients with subsequent pregnancies. The most recent and largest series states simply, "We have reviewed patients whose case histories are currently available."<sup>16</sup> Since cases over the decades have been obtained in these reports from the many clinicians' memories, and since it is human nature to remember those who have been seen more recently, the design of these studies is predisposed to find and report on the patients who are alive, which is a recollection bias.

For all of these reasons, each report contains a small fraction of such patients from that institution. An example is a typical series from the Memorial Sloan-Kettering Cancer Center: over 30 years, 41 stage I and II patients were found who became pregnant after breast cancer treatment, and they had an outstanding 80% five-year survival.<sup>13</sup> However, based on the numbers and ages of women seen in those 30 years, as we were able to obtain from the Memorial Hospital Tumor Registry, and

assuming only 7% of breast cancer patients less than 40 years of age became pregnant, this study should have reported on at least 450 women. Therefore, the patients reported from Memorial Hospital represent a highly selected subset, possibly 10% or so of the total who became pregnant after breast cancer treatment.

## Population-Based Reports

In an effort to avoid recollection bias, three large, population-based studies<sup>18,20</sup> have been published in the last five years. These studies are similar because they all depend on the National Health Service record keeping and a unique identifying number that is assigned to each person at birth and is used for every hospitalization and reportable event such as a cancer diagnosis.

The Finnish population-based study<sup>18</sup> used the personal identification numbers of women with a breast cancer diagnosis and searched the national birth certificate database for the years following their diagnosis. They found 91 eligible patients with subsequent deliveries and matched 471 control subjects for stage, age, and year of breast cancer diagnosis. The control subjects had to be alive for the same time interval as that from diagnosis to delivery of their matched cases. Breast cancer survivors with a subsequent birth after their diagnosis had statistically better survival rates than control subjects of the same age and stage with no subsequent births. The control subjects had a 4.8-fold (95% confidence interval [CI] 2.2-10.3) increased risk of death compared with those who delivered after the diagnosis of breast cancer.

The major flaw of national cancer registry information is that only dates of diagnosis and death for both patients and control subjects were available, with no information on recurrence. It is likely that breast cancer patients who chose to become pregnant and give birth were disease free, as opposed to an unknown proportion of control subjects who may have had a recurrence at the time of matching but had not yet died. Thus, this bias may have contributed to control subjects having a poor survival rate and thereby making the cases appear to have a particularly good survival rate. The authors termed this bias a "healthy mother effect" to denote that tumor registry matching design chosen did not overcome the fact that women without recurrence were more likely to become pregnant.

The second published study is from the Stockholm Breast Cancer Study Group.<sup>19</sup> This 1995 Swedish study also addressed the influence of subsequent pregnancy on breast cancer prognosis. The study population consisted of 2,119 women with primary operable breast

# Studies on Breast Cancer After Pregnancy

Author	Year	Number of Patients	Study Period	10-Year Survival Node Negative/Positive
Harvey et al <sup>13</sup>	1981	41	1940-70	80% / 79%
Ribiero et al <sup>23</sup>	1986	57	1941-80	64% / 26%
Mignot et al <sup>14</sup>	1986	68	1940-85	90% / 71%
Ariel and Kempner <sup>15</sup>	1989	46	1950-80	76% / 56%
Clark and Chua <sup>16</sup>	1989	136	1931-85	64%
Sankila et al <sup>18</sup>	1994	91	1967-89	93%
Von Schoultz et al <sup>19</sup>	1995	50	1971-88	*
Kroman et al <sup>20</sup>	1997	173	1978-95	*

\* 10-year survival not given.

cancer who were less than 50 years of age and were treated in the Stockholm region between 1971 and 1988. The study population was matched to the Stockholm County Council inpatient care registry — by computerized record linkage through use of the unique personal identification number — to obtain information about the patient's pregnancy history. A total of 50 pregnancies in 2,119 patients occurred after the diagnosis of breast cancer. The relative hazard adjusted for nodal status and age was 0.48 (95% CI 0.18-1.29) at a median follow-up of 7 years (range = 1-19 years). This was also the first study to report on estrogen receptor status, which was recorded in 70% of patients. The women with subsequent pregnancies had better survival rates if their cancer had positive estrogen receptors, which at first seems counterintuitive. However, this finding may be related to the fact that women with positive receptors have better survival rates and no micrometastatic disease.

The third of the population-based studies is from Denmark.<sup>20</sup> The study used computer linkage of the national records of Denmark on births, abortions, and breast cancer diagnosis. The authors identified 173 of 5,725 women with primary breast cancer aged 45 years or younger who became pregnant after treatment for breast cancer. Women who had a full-term pregnancy after treatment had a nonsignificantly reduced risk of dying (relative risk = 0.55, 95% CI 0.28-1.06) compared to women with no full-term pregnancy ( $P=0.08$ ).

Unlike the Finnish study, the authors attempted to adjust for recurrence. Because virtually all women who undergo subsequent pregnancy are recurrence-free, the need for appropriate recurrence-free control subjects for matching is important but very difficult. In the Danish study, computer-matched linkage was accomplished for 93% of patients, and information on recurrence was

available on 82% of them. However, it is unclear how carefully recurrence was sought and diagnosed. Furthermore, in an attempt to include as many pregnancies as possible, they entered cases up until 1994, and thus some had a limited follow-up of approximately one year. The population-based studies try to avoid the recollection bias prevalent in the retrospective studies, but they add biases perhaps in the choice of control subjects for the matching. These three studies add to the retrospective studies that show no detriment to subse-

quent pregnancy after breast cancer treatment. However, peculiar biases to each type of study exist. The Table is a summary of the studies on subsequent pregnancy.

## Future Studies and Advice to Current Patients

Only a study in which the patients are enrolled at diagnosis would provide comprehensive information on each patient at baseline, including clinical characteristics, treatment variables, and then a follow-up for medical status, recurrence, or any reproductive events. However, a prospective trial design is lengthy and expensive, with the goals obtained perhaps 10 years after its inception. The US Army, The University of Texas M.D. Anderson Cancer Center, Bowman Gray University, and Memorial Sloan-Kettering Cancer Center have launched a federally funded study accruing young women within eight months of diagnosis. Data are being collected on menstrual cycles, quality of life, and any reproductive events.<sup>21</sup> The short-term goal is the study of premature menopause, addressing symptoms, and sexual dysfunction, and the long-term goal is to obtain information on subsequent pregnancies. No inpatient visits are necessary; all information is obtained by mail or telephone. The study intervention consists of medical record data, menstrual cycle diaries, and questionnaires.

Unfortunately, statistics on survival following subsequent pregnancy will not be forthcoming for several years. We currently tell our patients that there are reports of more than 1,000 women who have undergone subsequent pregnancy and appear to be doing well. We also comment that we do not believe that these studies are as conclusive as studies that deal with risk of recurrence, eg, those offering hormonal therapy



or adjuvant chemotherapy for women with negative lymph nodes. Depending on the educational background of the patient, we discuss specific study design limitations: the anecdotal nature of the retrospective series in which the total population of those who had subsequent pregnancy is not known and the insufficient data available for choosing control subjects in the more recent population-based surveys.

After she is fully informed, the decision to become pregnant rests with the patient. Physicians are required to strike a balance between the uncertainty surrounding the safety of pregnancy and the need to restore a healthy and hopeful life, which for many young women includes childbearing. Other specific issues,<sup>22</sup> such as interest in adoption, may also be part of the discussion with the patient.

*Editor's note: Grant DAMD 17-96-1-6292 has been awarded by the US Army Medical Research and Material Command, Fort Dietrick, Md, for a prospective study on the effects of breast cancer treatment. Patient referrals can be directed to Dr. Petrek at (877) 636-7562.*

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## SHARE GOES GLOBAL

*By Marcia Presky, Odette Petersen  
and Jane Soyer*

Most people think of SHARE as a New York City based organization serving people with breast or ovarian cancer and their families and friends. It is all that—and more. For several years SHARE has been teaching people in other parts of the US and the world how to create similar organizations.

SHARE's peer model makes it easier to empower grassroots movements, because the information offered is from cancer survivors themselves. SHARE's representa-

tives have been trained to adapt the model in ways that are culturally appropriate in diverse populations.

### Czech Republic

SHARE and the American Jewish Joint Distribution Committee (JDC) implemented a first-of-its-kind partnership through a U.S.-government-funded project in 1995. Three teams of SHARE representatives visited Prague and Brno, facilitating workshops for breast cancer survivors from around the Czech Republic.

The workshops helped the participants identify concerns and problem-solve such issues as the severe lack of early detection programs, equipment and support services; inadequate doctor-patient communication; and outdated treatments.

Dramatic results are still being seen today. New public education programs have been implemented, more women now demand screening and effective advocacy efforts are bearing fruit.

### Poland

In June 1996, Sandra Zook-Fischler and Marcia Presky participated in a first-ever breast cancer conference in Krakow, Poland. After the confer-

ence, the SHARE/JDC representatives met with policy-makers, survivors, and medical professionals to design a project for Polish women with breast cancer. Funding is now being sought to implement this project, which is based on the successful Czech Republic and Israel models.

### Israel

The Women's Health Empowerment Project, begun in March 1997, was a partnership among SHARE, JDC, Israel Association for the Advancement of Women's Health and the Israel Cancer Association. In just over two years, new forms of education, self-help, and support activities have begun for women with breast cancer, and the general public.

The generous support of Andrea and Charles Bronfman brought together medical, government, and other organization representatives and women with cancer to address unmet needs. The project emphasizes SHARE's peer support model.

The SHARE team traveled around the country to work with members of the secular and ultra-Orthodox Jewish and Arab communities, as well as with immigrants from the former Soviet Union.

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## Medical Updates

by Susan M. Cohen

**New cancer study of New York City residents** – A consortium of 25 medical schools, medical centers and research institutions will track 300,000 NYC residents for 20 years. Information will be gathered about genetic and environmental factors that may increase cancer risk, as well as medical histories and lifestyle data. A diverse ethnic mix of healthy men and women ages 35 to 64 is sought. *For more information call the Academic Medicine Development Company at (212) 218-5640.*

**How does breast cancer treatment affect menstrual cycles and quality of life?** Memorial Sloan-Kettering Cancer Center and Wake Forest University are conducting a 3-year study. Data will be collected through a series of questionnaires from 800 women ages 18-45. Those with regular menstrual cycles diagnosed with invasive breast cancer within the past 8 months are eligible. *For more information, call Joanna Winawer at (877) 636-7562.*

**Margin width in surgical removal of DCIS may be an important determinant of local recurrence and need for postoperative radiation therapy.** DCIS (ductal carcinoma in situ) is a noninvasive cancer that is unlikely to recur if completely removed. *The New England Journal of Medicine* (5/13/99) reported that the distance between the boundary of a DCIS lesion and the edge of the surgically removed tissue may influence the likelihood of local recurrence. Postoperative radiation therapy doesn't appear to benefit patients whose margin width is 10 mm. or more. However, those with widths less than 1 mm. showed lower risk of

recurrence with radiation. The chance of the cancer reappearing after 8 years was 4% in patients with at least a 10 mm. margin and no radiation, but 50% for those with margins of less than 1 mm. and no radiation.

**Potential predictor for breast cancer risk identified** – *The Annals of Internal Medicine* (2/16/99) reports that scientists at the University of Pittsburgh have developed a simple blood test that measures serum levels of the hormones estradiol and testosterone. Women with the highest levels of either hormone were 3 times more likely than expected to develop breast cancer. This test is not yet available commercially.

**Two-year follow-up results from the Herceptin trial** announced at the American Society of Clinical Oncology Meeting revealed that women who had received Herceptin therapy had a median increase in survival of 4 months. This benefit would probably have been larger, but 65 % of the women who were in the chemotherapy-only arm of the study were allowed to take Herceptin after their disease progressed. This finding is exciting, as most therapies for metastatic disease extend time to disease progression, but do not usually extend overall survival.

**Pregnancy after breast cancer** doesn't appear to increase the risk of cancer recurrence or death from breast cancer, according to a report in *Cancer* by researchers at the University of Washington. The women who became pregnant did have a 70% higher rate of miscarriage than expected, with 24% of the pregnancies ending in miscarriages.

**More results from the Nurses' Health Study** – Harvard School of Public Health research reported in the *Journal of the National Cancer Institute* confirms the benefits of fruits

and vegetables in reducing the risk of breast cancer in some women. Premenopausal women who ate 5 or more servings of fruits and vegetables each day had a 23% lower risk of breast cancer than those who ate less than 2 servings a day. Postmenopausal women showed no benefit except for those taking hormones.

## New Legislation

**Effective April 1999, mammography centers are required by the Food and Drug Administration to:**

- Directly notify women about their results within 30 days;
- Provide a simplified report and a doctors copy to women with no designated health care provider;
- Write the notification in easy-to-understand language;
- Contact the patient if there is a suspicious finding, unclear or incomplete results, as soon as possible, ideally within 5 days;
- Transfer original scans to a patient's physician, or to the patient upon request.

**New York State Law now gives patients the right to an external appeal when health care services are denied on the basis that the services are medically unnecessary or that the services are experimental or investigational.**

*For more information, contact the NYS Insurance Department at 800-400-882.*

## On The Waterfront

Coming Soon: Landscape of Leisure for East River

By Timothy McDarrah, p. 20



### RUN-ON SENTENCING?

Can Legislation Deter Rapists?  
East Side Leaders In  
Controversial Debate. p. 6



### EDITORIAL

#### End Near For Mitchell-Lama?

**T**here are few issues of more immediate concern to most New Yorkers than the cost of shelter.

Only in New York do elementary schools have vocabulary words like rent control and rent stabilization, mortgage rates and tax deductible interest, brokers fees, security deposits, and key money.

Three decades ago, two enlightened state legislators sponsored a housing bill that led to tens of thousands of middle class New Yorkers being guaranteed quality housing at affordable prices.

New Yorkers who lived in Mitchell-Lama buildings enjoyed service and accommodation equal or superior to many luxury buildings. The residents for the most part cared about their homes and surroundings and worked hard to maintain their buildings, therefore making the surrounding neighborhoods more desirable as well.


There was a provision in the original legislation allowing management to essentially take the buildings "private" after a set period of time, a period which is now for many of the original Mitchell-Lama buildings.

The project that is of immediate concern here is the Ruppert-Yorkville Towers complex at 1601-41 Third Ave.,

CONTINUED ON PAGE 4

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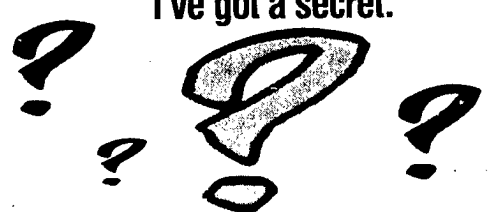
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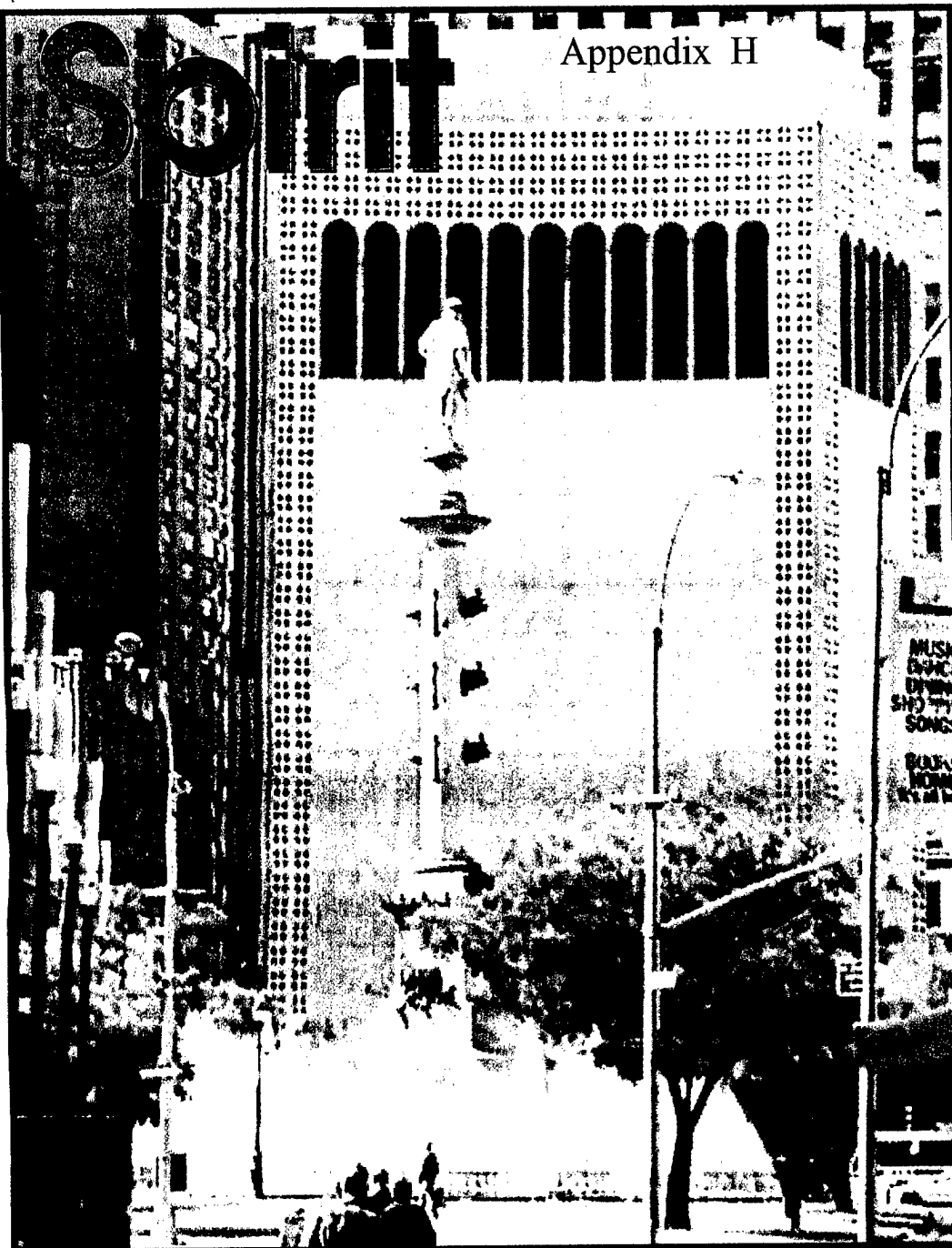
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Appendix H

# THE ART OR THE DEAL

*Will The West Side's Most Unusual Building Be Preserved as a Museum or Razed for Another Trump Hotel?* By Monica Rivituso, p. 20

DAVID DINKINS' REVENGE, p. 7 • INTRODUCING "THE BACK PAGE"

## EDITORIAL

### Give Me Shelter

There are few issues of more immediate concern to most New Yorkers than the cost of housing.

Only in New York do the vocabularies of grade-school students include such words as rent stabilization, vacancy decontrol, or key money.

And this obsession is understandable. After all, there are fewer places in the world where land costs more than in Manhattan.

Apartments that rent for under \$1,000 a month are the rarest of finds — even if they turn out to be boxy studios no larger than quarters in a monastery. And finding a Manhattan apartment for less than \$500 is an event so rare that it's newsworthy — or at least worth a mention in the gossip pages.

In years past, the West Side had been celebrated for its diversity. After Greenwich Village became too chichi for members of the struggling middle classes, the West Side still had a few neighborhoods and buildings where people earning less than six figures a year could live. For years, dancers and musicians, teachers, social workers, and writers all found a home on the West Side. Even after the Upper West Side became inundated with financial types in the '80s, reasonable rentals could still be found in Chelsea and Clinton.

And even when there was no time or money to find bona fide apartments, there used to be other options on the West Side. Hotels that rented single rooms by the week were once affordable alternative for many just arriving in the city. Some tenants stayed for only a short while, until they found their own apartments; others stayed on for years.

But now, as has been extensively reported, such alternatives are fast disappearing, as landlords are doing everything in their power to convert these lodgings into tourist hotels.

This week, the West Side is losing another source of affordable housing. The Leo House Annex, which has provided low-cost housing to single women since it was founded, will finally succeed in ridding itself of all

CONTINUED ON PAGE 4

# Rantz

## SOME THINGS THAT MAKE MY SKIN CRAWL

BY MALACHY MCCOURT

By the time you read this I'll be in Ireland with my friend and spouse, Diana. They do not have Thanksgiving there and thus we will be spared the sight of politicians trying to obliterate the indigent population by stuffing them with mega-cholesterol food and getting photographed by the press as if they were doing good for humanity.

So here are some no-cholesterol thoughts to chew on which might have the added effect of exercising your wrath and the blood pressure:

- What do you think of a person who uses the phrase "I only" — when talking about drinking (i.e. "I only drink wine and beer"; "I only drink martinis because I like olives")?

- I distrust a person who smells the wine bottle cork and/or sends back the wine.

- What do you think of people who knock on formica and then their own heads? Isn't that funny? Ha, Ha, Ha.

- Watch out for young men who smoke pipes. They are generally idiots!

Watch out for young women who smoke cigars. They are generally idiots!

- At what age do you have to think that perhaps it's not a fart?

- Why do some women pluck their eyebrows to the point where they look like worms with severe anorexia?

- I can't stand Americans who affect an English accent. Ditto Irish people who affect an English accent. Ditto English people who affect an English accent. In the dictionary, you will find English between enema and entrail.

- Some very creative chaps will tell you that you can't get pregnant if you do "it" standing up. Women, of course, do not trust the guy who promises to pull out before he comes or will put it in a little way and who sez, "If you love me you won't blabber about wearing a condom."

- I really trust the politician who sez he represents all the people. Not for one fleeting moment would I ever think a politician can be influenced by people who make large contributions to his campaign. I distrust tattooed politicians. I distrust tattooed anybodyes.

- I have to repress the urgent need to vomit when someone sez, "I like people" and the sincere asshole who announces, "I don't care if a person is black, white, red or yellow," as if to show how unbigoted they are.

- What about the bore who announces he doesn't want any grieving and weeping when he dies and wants everyone to have a good time? (This jerk doesn't know people will enjoy themselves simply because he is not infesting the earth anymore.)

- Some assholes prefaces many a statement with: "I'm the sort of person that..." while the world waits with suppressed breath for his views on stuffed cabbage.

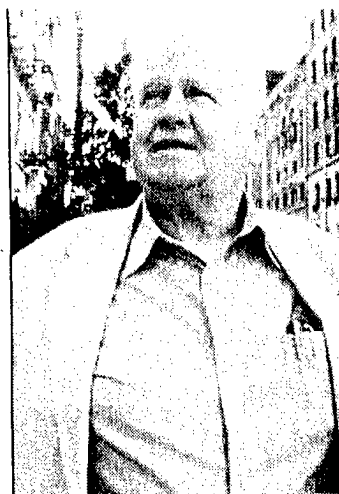
- Why do low-I.Q. right wingers always call radio shows and begin each outbreak with, "I'm sick and tired of..."?

- Other excrecences on the skin of our society are astrologers and radio astrologers anywhere.

- The idiot who sez his grandfather smoked 90 cigarettes a day, drank a quart of whiskey and had steak and eggs for breakfast and lived to be 113 years.

- Comedians who condescendingly say, "You've been a really great audience."

- What in hell do they mean when they report "a near-miss" when two aircraft nearly collide? "Near-hit" perhaps?



- I propose capital punishment for politicians who tell lies and parents who smoke in confined spaces while children are present. People who say, "Have a nice day" and those who oppose abortion rights for women.

- And theatrical agents who tell actors they loved your audition and you but they decided to go in a different direction. (I'd rather hear they hated me but I got the job.)

- Lastly, watch out for people who write long lists of complaints about unrelated subjects; there's an obvious attention deficit problem there.

Sez I to myself.

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## Thousands Sign Petitions Backing Parents' Plan to Restructure M.S. 141

By ANDREW WOLF

Thousands of residents of the Riverdale and Kingsbridge communities have already signed petitions demanding the restructuring of M.S. 141 into a Riverdale/Kingsbridge Academy, covering grades 6 through 12. Former New York State Attorney General G. Oliver Koppell, the interim head of the newly formed Riverdale/Kingsbridge Educational Advocacy Committee (R/K-EAC), said Monday that he anticipates that the goal of 3,000 signatures will be "easily reached, and probably exceeded."

Exactly where and when the petitions will be presented to Superintendent Irma Zardoya and Community School Board

10 has not yet been determined. The Superintendent postponed the planned November 23rd release of her plan. This is thought to be related to the powerful presentation made by the R/K-EAC at a meeting with top Board of Education officials on November 17th.

At the same time, in the absence of action by District 10 officials, sentiment may be growing for the introduction of a resolution at the December 17th Community School Board meeting based on the "10-Point Plan" developed by the P.S. 24 Parents Association, and endorsed by the R/K-EAC. Three school board members have lent their names to the effort of

*Continued on Page 3*



Vol. VI, No. 6

December 3 - 9, 1998

# Mosholu Golf Course Selected by City As Surprise Choice for Filtration Site

By SONDRA LEVIN

The Department of Environmental Protection's (DEP) choice of the Mosholu Golf Course as its preferred site for a filtration plant is a blow for some Bronx activists, community leaders and park advocates who opposed the placing of the plant in the Bronx, but the decision is a victory for the neighborhoods and schools surrounding the Jerome Park Reservoir and for city unions and the construction industry.

The DEP announced on Tuesday that it chose the Mosholu Golf Course site in Van Cortlandt Park as its preferred site for the federally mandated filtration plant for the Croton Reservoir system.

As two of its major reasons for selection of the site from 17 alternative configurations, the DEP said in a press release, "The golf course site would result in the least potential for significant impacts during construction, and there would be no significant impacts posed by operation of the filtration plant facilities."

The DEP pointed out that one major benefit of the golf course site is that it allows for the plant and all related facilities to be built at one location. The related facilities are a 20-million gallon treated water reservoir and the finished water pumping station.

The construction costs for the plant are expected to be \$660 million and the annual operations and maintenance costs are projected to be \$11 million, according to the DEP. Construction will begin in the year 2001 and is projected to be completed by the year 2006.

According to one Bronx



Ralph Calderon sinks his putt on the Mosholu Golf Course, enjoying the unseasonably mild weather Tuesday. The golfer was shocked to learn that the course may be closed in the year 2001 to make way for the federally-mandated Croton Water Filtration Plant.

leader, the DEP appears to have chosen the Bronx site with the least amount of opposition.

Sources said that some park "advocates" pushed for the Mosholu Golf Course site behind the scenes as their preferred alternative if a site had to be picked in the Bronx. They felt that construction at the golf course would be the least destructive to trees and undeveloped forest areas, according to the sources.

Considering that the Jerome Park Reservoir was the original preferred site by the DEP, Bronx leaders said the DEP's latest choice of a site represents real progress in the 10-year community battle against the filtration plant.

It is considered a major victory for the Bronx opponents of the plant that the DEP rejected the site of Jerome Park Reservoir, which was unanimously opposed by Bronx elected and community leaders.

While all Bronx elected leaders opposed the use of any Bronx sites for the filtration plant, New York City union locals and contractors in the building trades and construction industry supported use of the Shandler Recreation Area, claiming that use of this site would keep jobs in the city. The golf course site would also serve this purpose.

Concern was expressed by leaders that the golf course site is close to the Norwood commu-

nity and a major hospital. The site's southern boundary is at the northern tip of the Norwood community and the site is just blocks away from Montefiore Hospital.

Bronx elected leaders and activists have repeatedly said that the DEP should focus more attention on non-filtration methods including cleaning up the pollution in the reservoir's watershed. They said that if building a filtration plant can't be avoided, the next best option is to place the plant in Westchester County.

Explaining the DEP's choice of the golf course as a site, a DEP statement said, "Other sites were rejected because they either presented unacceptable operational risks or would result in signifi-

cant neighborhood and environmental disruptions that could not be reasonably mitigated."

It said, "Specifically three of the Westchester alternatives would rely on the transfer of all Croton system water into the Catskill/Delaware system, resulting in 100 percent reliance on the DEP's Hillview facilities for all supply to the city." The DEP also said that all the Westchester sites would require split facilities with significant construction in the Bronx for the plant's related facilities."

Explaining why the other Bronx sites were rejected, the DEP statement said, "These sites would result in significant disruption to surrounding residents and schools, require removal of publicly-accessible ballfields and picnic areas during construction and the permanent loss of old growth forest."

### Battle to Continue

Activists and elected leaders said they will continue to fight the preferred site selection with a variety of actions ranging from opposition during the Uniform Land Use Review Process (ULURP) to seeking federal help.

Upon hearing the news of the city's choice of the golf course for a preferred site, Tina Argenti, a leading activist for over ten years in the filtration plant issue and president of the Friends of Jerome Park Reservoir, sighed and said, "That's a shame."

She explained her statement saying, "It is good news for Jerome Park Reservoir, but it is sad they want to use a recreational area."

Argenti said the choice of the *Continued on Page 28*



## Einstein Seeks Volunteers for Prostate Cancer Study

Albert Einstein College of Medicine of Yeshiva University has launched a project, called STOPCancer, which will investigate the causes of prostate cancer. To do this, the College is asking for male volunteers, over the age of 50, who have never been diagnosed with cancer.

"We will compare the lifestyle, genetic and dietary factors of these volunteers with the same factors in patients of similar age and ethnicity who have prostate cancer," explains Dr. Gloria Ho, principal investigator of the study and associate professor of epidemiology and social medicine.

Volunteers will be asked to complete a screening form and then undergo a one-

time free physical examination at the College of Medicine. They will be reimbursed for transportation and receive the results of tests relating to their health. Study participants will not be required to take medications or change their dietary habits.

Prostate cancer is the most common cancer affecting men in the United States and the second leading cause of cancer deaths in males. One in 5 men will develop prostate cancer in their lifetime. "If

we can determine the causes of prostate cancer, we can begin to control and prevent it," said Dr. Ho.

To volunteer for the STOPCancer study, call (718) 430-3418.

## HEALTH WATCH

## Ophthalmology Dept. Receives Award to Study Cataracts

The Department of Ophthalmology at Montefiore Medical Center and the Albert Einstein College of Medicine has received a four-year, \$165,000 career development award from Research to Prevent Blindness (RPB) to study how cataracts are formed.

The grant will be used to further the studies of Ales Cvekl, Ph.D., an ophthalmologic molecular geneticist who has conducted pioneering work in cataract formation at the National Eye Institute of Health and was recently hired by the Department of Ophthalmology.

"We are extremely grateful to Research

to Prevent Blindness for this grant and we are excited to have Dr. Cvekl join our team and continue to make inroads into cataractogenesis, a dysfunction that leads to one million operations every year," said Ronald Burde, M.D., chairman of Ophthalmology at Montefiore and Einstein.

The RPB's Research Career Development Award, which now totals \$13 million, was established in 1990 to attract young physicians and basic scientists to research position in departments of ophthalmology at universities across the country.

## New Family Care Centers Opens at Montefiore Medical Center

Montefiore's new Family Care Center brings together two outstanding Montefiore programs — its Department of Primary Care Medicine and Ambulatory Care Center. The Family Care Center offers neighboring Bronx residents compre-

hensive, top quality outpatient care at one site. The single location makes referrals from primary care physicians to specialists more efficient and practical. It is expected to provide more than 210,000 primary and specialty care visits annually.



Pictured from left: Elaine Brennan, senior vice president, Operations, Montefiore Medical Center; Kenneth Hupart, M.D., medical director, Ambulatory Care Center; Mutya San Agustin, M.D., director, Department of Primary Care Medicine, Montefiore Medical Center; Assemblyman Jeffrey Dinowitz; and Spencer Foreman, M.D., president, Montefiore Medical Center.

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### FAMILY HISTORY OF MEMORY LOSS OR ALZHEIMER'S DISEASE?

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### JEWISH MEN who have or had PROSTATE CANCER

If you were diagnosed at age 65 or younger, OR at any age and also have a father, brother, son or uncle who has or had prostate cancer, then you are eligible. To participate, all you need to do is fill out a questionnaire and give an inner cheek cell sample. No travel is required.

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## Appendix K

Cancer and Treatment  
Information

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## A Study of Breast Cancer and Its Effect on Premature Menopause and Quality of Life

*If you were recently diagnosed with breast cancer  
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**You can help shape the future of breast cancer treatment for women by participating in this important study being conducted by physicians around the country, including physicians at Memorial Sloan-Kettering Cancer Center. A total of 800 women are needed to participate in this three year study.**

### The purpose of the study

It is known that some breast cancer treatments can affect a woman's menstrual cycle and possibly cause premature menopause. The occurrence of these symptoms and their duration depends on many things including the type of drugs taken, the dosage, and the woman's age. This study was designed to determine how various breast cancer treatments affect a pre-menopausal woman's menstrual cycle and assess the subsequent changes to her quality of life. Women's response will provide valuable information for future breast cancer patients who seek to better understand treatment options and how they may affect women's lives.

### Participation eligibility

To participate in this study, you must:

- Be **45 years of age** or younger
- Have been diagnosed with stage I, II or III breast cancer **in the past 8 months**.
- Have had **regular menstrual cycles** at the time of diagnosis

### Participation is easy

Women can participate in this study through postal mail. No in-person visits are necessary. An initial questionnaire will be sent to all study participants followed by additional questionnaires every six months. Every woman in the study will be provided with menstrual cycle calendars for the duration of the study.

### Help support learning for future breast cancer patients...

*For additional information about this study please contact Joanna Winawer at Memorial Sloan-Kettering toll free at (877) 636-7562 or [winawerj@mskcc.org](mailto:winawerj@mskcc.org)*

*Jeanne Petrek, MD, Principal Investigator.*

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[Memorial Sloan-Kettering Cancer Center Home Page](#)

Search

# Center

JUNE 1999

## New Members Elected to Board

Two new members have been elected to the Board of Overseers of Memorial Sloan-Kettering Cancer Center: William B. Harrison, Jr., and Clifton S. Robbins.

Mr. Harrison, a Director of The Chase Manhattan Corporation and The Chase Manhattan Bank, became Chase's President and Chief Executive Officer on June 1. He is also a director of Dillard Department Stores, Freeport-McMoRan Copper & Gold, Inc., and the United Cerebral Palsy Research and Education Foundation. He is a member of The Bankers Roundtable, the Board of Directors of Banco General de Negocios, the Board of Trustees of the Central Park Conservancy, and Carnegie Hall. Mr. Harrison is a graduate of the University of North Carolina and Harvard Business School's International Senior Management Programme.



WILLIAM B. HARRISON, JR.



CLIFTON S. ROBBINS

Mr. Robbins is a General Partner of Kohlberg Kravis Roberts & Co., which primarily makes equity investments in leveraged buyouts. He is also a member of the Board of Directors of Borden, Inc., IDEX Corporation, KinderCare Learning Centers, Inc., Newsquest Media Group Ltd., and Regal Cinemas, Inc. He is a trustee of the Central Park Conservancy, Chairman of the Board

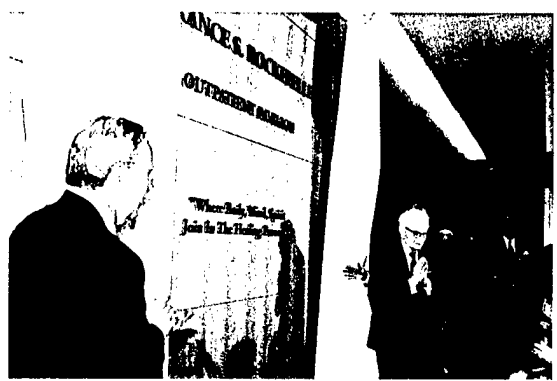
CONTINUED ON PAGE 7

## Laurance S. Rockefeller Outpatient Pavilion Dedicated with Warmth & Joy

With great excitement and anticipation, the Laurance S. Rockefeller Outpatient Pavilion, Memorial Sloan-Kettering 53rd Street was dedicated on April 19. The new facility — named in honor of Mr. Rockefeller, Honorary Co-Chairman of the Boards of Overseers and Managers — is located at 160 East 53rd Street, at Third Avenue, and offers the best of outpatient cancer care and innovative programs in women's health, cancer prevention and wellness, and integrative medicine.

"Memorial Sloan-Kettering has been known as a caring institution," Mr. Rockefeller said at the dedication ceremony. "With this new facility and the new programs being initiated, we have the ongoing opportunity to further enhance our ability to provide compassionate, as well as excellent, care." "Laurance Rockefeller's vision for Memorial Sloan-Kettering as a world-class cancer center has been turned into a reality because of his remarkable willingness to take the risks and make the bold moves that pushed this institution to new heights," said Douglas A. Warner III, Board Chairman.

The ceremony took place in the pavilion's lobby, where the main physical feature is a sculptural water wall — a ceiling-high stone backdrop with a gentle waterfall, in front of which stands a delicate brass screen depicting a willow tree. Some 240 MSK friends and staff members shared in the



MSKCC PRESIDENT DR. PAUL A. MARKS (LEFT) AND LAURANCE S. ROCKEFELLER, HONORARY CO-CHAIRMAN OF MSKCC'S BOARDS OF OVERSEERS AND MANAGERS, UNVEILED THE COMMEMORATIVE WALL AT THE LAURANCE S. ROCKEFELLER OUTPATIENT PAVILION, MEMORIAL SLOAN-KETTERING 53RD STREET.

dedication. "You could feel the excitement of the staff, the energy, the feeling that something extraordinary was happening," said Wendy Perchick, the pavilion's Executive Director.

Following the dedication, throughout the day, upward of 700 guests and MSK staff toured the pavilion's ten floors — each of which, Center President Dr. Paul A. Marks pointed out, in reference to a quotation on the wall, "was created to symbolize the wholeness of body, mind, and spirit."

For more on the dedication ceremony and information about the Laurance S. Rockefeller Outpatient Pavilion and the services and programs housed there, see this issue's special insert section.

## Dr. Anderson Named to PaineWebber Chair

MSKCC has appointed Dr. Kathryn V. Anderson, an internationally known developmental biologist, to the newly created PaineWebber Chair in Genetics.

Head of SKI's Developmental Genetics Laboratory, Dr. Anderson is conducting path-breaking research on the primitive immune system of the fruit fly, *Drosophila*. She is investigating the fruit fly's immune system through studies of its genetic signaling pathway, which instructs cells of the



DR. KATHRYN V. ANDERSON

embryo to develop into different types of cells — muscle, skin, or nerve, for example. Her work includes research showing that the fruit fly and human immune systems have structurally similar components — findings that are proving to have significance to the field of human immunology.

Dr. Anderson is also analyzing genes that control signaling pathways in mice, including genes that control neural tube defects such as spina bifida, one of the most common birth defects in humans.

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# Interview...

## ...with Dr. Jeanne A. Petrek

People who have some curiosity, no matter what kind of work they do, probably spend some time saying to themselves, "Now, wait a minute. If I do this *this* way, maybe it'll be a little bit better and the next step will be easier. Or maybe it won't. Let me try it."

We see so many breast-cancer patients here that it is a shame not to learn more about the disease from them, and to make treatment better in the future. If you don't do clinical research, you're seeing one patient after another and you're not doing anything different — not thinking about how you could make things better.

Breast cancer is hard to study because it has such a variable natural history. It's a heterogeneous disease, and the natural history can be very different from person to person. There are also a great many women who have very lengthy cases.

For people who really want to do research — and there aren't that many — the greater impetus now is to answer the big, important carcinogenesis questions, to study all this really hot stuff like sequencing the human genome. So these somewhat more quality-of-life issues haven't had a lot of attention.

It's really just since the breast-cancer advocates became active in the last ten years that we are finding money for quality-of-life studies. Breast-cancer research is finally getting a lot of funding, and that's what's been responsible for these great recent advancements in breast-cancer treatment like immunotherapy drugs that target specific receptors, paclitaxel and related drugs, and sentinel lymph-node biopsy.

The big study I'm working on now is a prospective, multicenter, five-year examination of premature menopause as a result of breast cancer and chemotherapy. Nothing is really known about premature menopause, so it's a fairly open question.

We're working with the world's experts in menopause in the normal woman. These researchers, who are at Wake Forest University, are doing a study on the quality of life and behavioral aspects of menopause in nearly 200,000 healthy women, a study called the "Women's Health Intervention." The researchers are interested in our young patients because they'll have some data for comparison. We can use some of the same questionnaires and standards and be able to say — which is my expectation — that it's even

more distressing to go through menopause at age 35 or 40 than at age 50.

Our study will address goals such as the determinants of premature menopause after breast-cancer chemotherapy and the resulting quality of life. We may, for example, discover that some chemotherapy agents are less likely to cause menopause. And if menopause, with all its symptoms, is so distressing, is it additive to the distress caused by breast-

cancer treatment or is it really inconsequential?

People have begun to question whether treatment that puts the very earliest stage patients into menopause at age 35 or 40 is worth the price of menopause or not. They have so many more years than the average woman to be menopausal, meaning increased risk of osteoporosis, heart disease, Alzheimer's — who knows. Are we doing them detriment by adding an extra 15 years of menopause?

I'm also working on a study, funded by the U.S. Army Breast Cancer Research Program, with patients in the Kaiser California system on pregnancy following treatment for breast cancer. Kaiser has very good records, in part because it is under a mandate to follow patients with a cancer diagnosis to see how they've

done, even if those patients go elsewhere. So we'll have good data for a retrospective study.

I recently finished a study, also funded by the Army, on lymphedema in breast-cancer patients up to 20 years after treatment. We found that at least 15 percent of the women had developed lymphedema measurable by a swelling of two centimeters or more in the affected arm.

As time goes on, I've become interested in more general questions in women's health. Recently, I spoke at the opening of a scientific exhibit on women's health at the Baltimore Science Museum. Because breast disease and breast cancer are so omnipresent,

they are a good lead-in to women's health in general. I've found that particularly interesting and a real learning experience. I get to speak a lot on women's health issues, or at least women's cancers. But the beauty is I actually get to learn all this great new stuff about women's health, so that breast cancer has been a platform to do even more for women.



**Breast-cancer research is finally getting a lot of funding, and that's what's been responsible for these great recent advancements.**

MSKCC INTERVIEW IS A REGULAR FEATURE IN WHICH CENTER CLINICIANS, INVESTIGATORS, AND OTHER STAFF PRESENT, IN THEIR OWN WORDS, THE LATEST INFORMATION ABOUT VARIOUS AREAS OF RESEARCH, CANCER TREATMENT, AND MATTERS OF INTEREST. IN THIS ISSUE, DR. JEANNE A. PETREK, DIRECTOR OF THE SURGICAL PROGRAM AT MEMORIAL SLOAN-KETTERING — 64TH STREET, SPEAKS ABOUT HER RESEARCH AND THE QUESTIONS THAT INSPIRE IT.

## Appendix M

Dear Joanna:

The newsletter below went out to 2,200 subscribers last evening, and it will go out to the remainder of 1,100+ Sunday afternoon. Unfortunately, I have some good news and bad.

I won't be able to finish the banner and put it into rotation until Wednesday morning, but the good news is that the 30 day period won't start till then.

Steven Craig Sickles  
President, BreastCancer.Net  
732.224.0402

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The BreastCancer.Net Newsletter for:

Monday, December 7, 1998

The BCN Newsletter is delivered free of charge to over 3,300 breast cancer survivors, health professionals, and legislators in 54 countries.

Links to all these stories, along with an archive of 1,500+ other cancer-related news items, are available 24 hours a day in our Newsroom at:

<http://www.breastcancer.net>

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BreastCancer.Net Breast Cancer Study Announcement  
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**A Study of Breast Cancer and Its Effect on Premature Menopause and Quality of Life**

Memorial Sloan-Kettering Cancer Center and the Wake Forest University School of Medicine in Winston-Salem, North Carolina, are initiating a study of how breast cancer may affect women's menstrual cycles and their quality of life. A total of 800 women are needed to participate in the study, which involves the use of questionnaires and menstrual-cycle diaries.

**\* Participation Eligibility**

To participate in this study, you must:

- Be between the ages of 18 and 45

- Have been diagnosed with stage I, II, or III breast cancer in the past 8 months
- Have had regular menstrual cycles at the time of diagnosis

\* How to participate

An initial questionnaire will be sent to all study participants, followed by additional questionnaires every six months. The initial questionnaire will take about 45 minutes to complete. Subsequent questionnaires will take 20 to 30 minutes. Every woman in the study will be provided with menstrual-cycle diaries, which they will fill out for the duration of the study.

The follow-up questionnaires will be sent from the Wake Forest University School of Medicine every six months for the full three-year duration of the study. Participants will receive a new menstrual-cycle diary every three months.

Other important facts about the study:

- No in-person visits are necessary to participate in this study.
- Study information will be kept completely confidential.
- Informed consent will be obtained from all participants.
- There are no medical or health risks associated with participating in this study.
- No blood or urine samples will be collected.
- There is no cost for participation in this study.
- Participation will not affect your medical care.
- Women who have participated in previous studies report their satisfaction at having made a contribution to breast-cancer research

If you would like to learn more about this study, please contact Joanna Winawer, research study coordinator at Memorial Sloan-Kettering Cancer Center, by e-mail at:

[winawerj@mskcc.org](mailto:winawerj@mskcc.org)

or call toll free: (877) 636-7562.

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1) Sibling Cord Blood May Offer Best Match Chance For Some Patients

[12/07/98; Doctor's Guide]

<http://www.pslgroup.com/dg/c9a12.htm>

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2) Breast Implant Battle's Other Complications

[12/07/98; Washington Post]

<http://search.washingtonpost.com/wp-srv/WPlate/1998-12/07/128I-120798-idx.html>

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3) Search for Answers Impeded by 'Noise'

## Appendix N


0 **The DVD-DAILY Magazine**  
News, Views & Reviews Delivered Straight to Your Computer  
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1 **Clinical Trials for Stage IV Breast Cancer  
and Stage III/IV Ovarian Cancer**  
The Garden State Cancer Center, a non-profit, NCI-funded institution, is now evaluating candidates for clinical treatment studies which utilize tumor targeted radiation delivered by anti-tumor monoclonal antibodies.  
For further information, call 973-844-7100, or email us at [gscancer@att.net](mailto:gscancer@att.net)

2 *Our goal is more than having a  
woman with breast cancer survive ...*



3 **Memorial Sloan-Kettering  
Cancer Center** **Reach Out and Help this Holiday!**  
A Study: Breast Cancer, Premature  
Menopause and Quality of Life  
For details on how you can contribute to breast cancer research by participating in this non-invasive survey-based study, click here ....

4  **Can soy protein promote breast health?**  
**FREE samples and literature**  
**1-800-500-2055**

5  **A Breast Cancer First-Aid  
Kit for the Heart & Soul**  
Between Us is a product designed by long-term breast cancer survivors to provide immediate comfort for women who have just been diagnosed.  
 *Click here!*

6  **national society of  
genetic counselors, inc.**  
[www.nsgc.org](http://www.nsgc.org)

7  **How can you get a free custom web page and ad  
banner made by a professional web development firm?**  
**For only \$50 !?**  
*Well, you start by clicking here ...*

8  **Ladies First** **1-800-497-8285**  
Helping women feel feminine and confident  
following breast surgery ...  *Click here ...*





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NEWS

NATIONAL ALLIANCE  
OF BREAST CANCER  
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VOLUME 13 NUMBER 2  
APRIL 1999

## Appendix O

### ABMT Findings Show Equivalent Survival

With the arrival of Spring, the breast cancer and cancer communities worldwide eagerly awaited news of the outcome of several breast cancer treatment trials, findings anticipated to either redirect or reconfirm a course of treatment for thousands of women with the disease. On April 15, 1999, the first glimpse of the trial results became available in the form of abstracts, four among the hundreds of breast cancer-related presentation summaries compiled for the American Society of Clinical Oncology (ASCO) annual meeting in Atlanta in mid-May. The large U.S. studies found that over follow-up periods averaging three years, autologous bone marrow transplantation (ABMT)-supported high-dose chemotherapy offers no significant disease-free or overall survival benefit compared with lower-dose standard regimens.

Research abstracts, paragraphs summarizing study design, hypotheses and conclusions, are prepared in advance of talks scheduled at the ASCO meeting. They are released to the Society's members and conference registrants a month before the meeting date, and posted on ASCO's website at [www.asco.org](http://www.asco.org). Two National Cancer Institute-supported studies and two foreign studies (from Scandinavia and South Africa) contributed information about ABMT in women with the most advanced stage breast cancer, as well as in those with aggressive cancer found in multiple underarm lymph nodes at first diagnosis. This puts them at very high risk of recurrence.

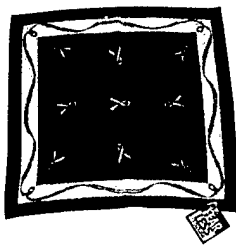
The two U.S. studies were randomized Phase III trials conducted by members of two cooperative research groups at numerous sites throughout the country. One, the Cancer and Leukemia Group B (CALGB) study, was begun in 1991 to examine the efficacy of high-dose chemotherapy followed by ABMT in almost 800 women whose breast cancer had spread to ten or more axillary lymph nodes. The women, who had a median age of 45, received either high-dose, cisplatin-based combination chemotherapy followed by ABMT or the same chemotherapy drugs at the highest possible dose tolerable without ABMT. At three years of follow-up, overall survival was 78 percent for women who had received ABMT, and 80 percent for those who had received lower dose chemotherapy. Both study arms showed higher survival rates than clinicians

### Women to Receive Mammography Results

Since national standards for quality assurance in mammography were made law in 1992, women no longer have to worry about whether they are receiving a safe, state-of-the-art imaging test. The Mammography Quality Standards Act (MQSA) passed in that year instituted a strict system of requirements that govern every aspect of the procedure. Now a woman need only look for the blue FDA certificate prominently displayed at each site; in fact, to be in lawful operation, a facility must not only have FDA certification, but show it is accredited by either the American College of Radiology or by certain states as well.

Until recently, however, MQSA regulations did not require facilities to give women understandable results of their mammograms, creating alarming vulnerability in the FDA's efforts to assure the highest-quality test. Modifications were made law by Congress at the urging of patient advocates: "Direct Patient Notification" requirements go into effect on April 28, 1999 as part of the Final MQSA Regula-

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Scarves Go  
to Work

SEE BOX, PAGE 3

This issue of NABCO News  
has been made possible by  
an educational grant from  
Glaxo Wellcome Inc.

CONTINUED ON PAGE 4

### STAR Set to Announce

The second large-scale breast cancer prevention trial (P-2) is in final preparations for a late-Spring launch, according to the National Cancer Institute and the NSABP, the cooperative research group administering the study. The "Study of Tamoxifen and Raloxifene," or STAR, will compare the efficacy of two FDA-approved drugs in reducing the incidence of invasive breast cancer in high-risk, postmenopausal women. Close to 200 sites and their satellites in the U.S., Canada and Puerto Rico are being readied to open accrual, and most of the NSABP membership is now sending the P-2 protocol through internal review.

Since its FDA approval for osteoporosis prevention, numerous media reports have noted the promising effects of raloxifene (Eli Lilly's Evista®) in reducing breast cancer, and some women at high risk for breast cancer have reportedly begun taking the drug without waiting to be evaluated for STAR. In February 1999, Zeneca, the maker of Nolvadex® brand tamoxifen, filed charges to halt alleged improper promotion of Evista to physicians by Lilly's sales force, who it claims has been routinely discussing raloxifene's breast cancer activity.

## NEWS briefs

**PUBLIC SECTOR** Recent efforts by President Clinton and others to make comprehensive patients' rights law gained some ground in March 1999 when a Congressional committee approved S 326, a Republican-backed version of such a bill, and referred it for full Senate consideration. While Democratic critics point to crucial protections (such as the right to sue HMOs) not in the G.O.P. bill, it would permit an estimated 120 million Americans enrolled in employer-sponsored health plans to appeal denied claims to independent medical reviewers. The National Patient Advocate Foundation is collecting signatures for its online Patients' Bill of Rights petition at [www.npaf.org](http://www.npaf.org). . The House has reintroduced The Breast and Cervical Cancer Treatment Act. It would give states the option to make Medicaid coverage available for cancer treatment costs of uninsured women under age 65 diagnosed through the CDC's national screening program for poor women. . In April, Senators Connie Mack (R-FL) and Jay Rockefeller (D-WV) reintroduced legislation that would ensure Medicare coverage for routine care received in approved clinical trials, citing that 60 percent of cancer deaths occur in the Medicare population. . The NCI has named Dr. Jeffrey D. White Director of its new Office of Cancer Complementary and Alternative Medicine, which will coordinate with all NIH institutes.

**RISK** The first study to demonstrate the ability of prophylactic mastectomy to reduce subsequent breast cancer incidence was published in the January 14, 1999 issue of *The New England Journal of Medicine*. Lead author Dr. Lynn C. Hartmann, an oncologist at the Mayo Clinic, updated and extended her ongoing retrospective analysis of a series of 639 women with family and/or personal histories of breast cancer who had undergone the procedure at Mayo from 1960 to 1993. The women on average were 42 years old when they elected prophylactic surgery. The researchers compared breast cancer cases in the highest-risk women to incidence in their sisters who did not undergo surgery. At an average of 14 years of follow-up, 38 of the untreated sisters had developed breast cancer compared with three cases in the post-surgical group. The reduction in incidence was more than 90 percent, with an even higher reduction in breast cancer deaths. Similar reductions were observed when comparing results from a widely-applied predictive model with cases in women in a moderate-risk group who had the surgery. Some experts found limitations in the study, including the variability of surgical procedure in U.S. institutions, and noted that confirmed genetic susceptibility—now thought

## Women Needed for Cycle Study

Memorial Sloan-Kettering Cancer Center in conjunction with Wake Forest University is conducting the first large scale study of how breast cancer treatment affects women's menstrual cycles and quality of life. Data will be collected through a series of confidential questionnaires to be completed by each participant over the three years of the study, for which a total of 800 women age 18 through 45 are needed. Eligible are those with regular menstrual cycles who were diagnosed with invasive breast cancer within the past eight months. No in-person visits are required. For more information, contact Joanna Winawer toll-free at (877) 636-7562.

to be a requirement for a woman to even consider the extreme and irreversible procedure—was not established in the women studied. The authors concluded that physicians and women should approach this option with caution, hoping that over time it would be replaced by the preferable alternative of safe chemoprevention. . Continuing the controversy over the role of dietary fat in breast cancer risk, the latest update of the Nurses' Health Study found no evidence that lower fat intake, or excluding any specific type of fat from the diet, are associated with a decrease in breast cancer cases. Dr. Michelle Holmes and colleagues reported the results of evaluating 89,000 women with a series of food frequency questionnaires from 1980 to 1990 (*Journal of the American Medical Association*, March 10, 1999).

**TREATMENT** Many breast cancers are diagnosed among the 38 million U.S. Medicare beneficiaries age 65 and up. Growth in Medicare's HMO program has stimulated research into the quality and standards of cancer treatment received by HMO beneficiaries. Gerald F. Riley and colleagues examined the SEER-Medicare database for differences in breast cancer stage and management in HMO and fee-for-service (FFS) settings (*JAMA*, February 24, 1999). Late-stage diagnosis was less frequent among HMO, compared with FFS, enrollees between 1988 and 1993. Use of breast conserving treatment (BCT, including radiation) in Stage I and II cases varied substantially by U.S. region, but overall rates were similar for both types of coverage. The 36 percent frequency of BCT noted in the study was much higher than Medicare rates in the late 1980's ....Beginning in January 1999, Medicare coverage was extended to certain FDA-approved oral "anti-cancer prodrugs", including Xeloda™ (capecitabine) tablets for advanced breast cancer. Once ingested, the drugs metabolize into the active ingredients found in injectable chemotherapy. ♀

## The Myths and Truths About BSE

Over the past decade, disagreement over issues of medical evidence and health care policy have thoroughly confused women searching for clear screening mammography recommendations. Thankfully now resolved, the mammography controversy alerted women that experts can disagree, and that recommendations will change with ongoing scientific developments. However, when it comes to the utility, necessity and performance of breast self-examination (BSE), most women are still in the dark.

BSE is the third "leg" of the breast cancer early detection triad recommended by most major U.S. cancer organizations, along with screening mammograms and clinical breast exams (CBEs). During the 1980's BSE was a favorite topic in cancer education materials written for the public: it was easy to illustrate using graphic swirls, arrows and line drawings; printing a BSE reminder on shower cards produced an inexpensive women's health giveaway; and BSE could be accomplished by a woman herself, almost anywhere free of charge. At that time, with many women's magazines reporting that breast cancers were "mostly found by women themselves," few cancer professionals questioned the BSE emphasis.

However, use of BSE has never been proven to benefit breast cancer survival, unlike regular screening mammograms and clinical breast exams. Both screening methods have been shown to reduce breast cancer deaths when used either independently or in combination. The reason for this is straightforward: women not trained by a doctor to perform BSE—and that is most women—cannot distinguish breast lumps less than one inch (2.5 cm) in diameter. At one inch or larger in size, if the lesion is breast cancer it may have already invaded the underarm lymph nodes or even internal organs, where the chance for cure is remote. To be most beneficial, early detection must find breast cancer when it is still contained in the breast as a lump so small that it can only be revealed by a physician's trained hands, or better yet, discovered by mammography before it can be felt at all.

By 1990, modern screening mammography was widely available and being reimbursed by insurers, and women were learning to "shop" for mammography facilities that were part of the American College of Radiology's voluntary quality accreditation program. In contrast to the one inch-plus size of lumps found by BSE, mammographically-detected breast cancer can be smaller than a pencil eraser. By 1995, government mammography regulations that required

## Scarves at Work for NABCO

Fashion and philanthropy go hand in hand this Spring as NABCO and Symphony Scarfs, a New York-based accessories manufacturer, join to fight breast cancer. Symphony has designed, produced and marketed a line of custom scarves to benefit NABCO, including a special "Pink Ribbon" scarf (pictured on page 1), currently on sale at major retailers such as Macy's, Lord & Taylor, Stern's and Rich's. Sales will support NABCO's Information Services and Education programs. Each scarf carries a specially-designed pink and black hangtag featuring NABCO's FEARLESS icon, along with an educational message and NABCO's toll-free number.

"With every woman at risk for breast cancer, we wanted to help NABCO raise awareness about the disease in this creative and fashionable way," said Rhonda Forster, National Sales Manager for Symphony Scarfs and a two-year breast cancer survivor. "Symphony wants every customer to take care of herself by starting her own breast health program, and give herself a beautiful scarf as a present." New Symphony styles will go on sale this Fall in time for National Breast Cancer Awareness Month.

FDA inspection and certification were in place, assuring women that the screening tests were safe and of high quality. The proportion of women age 40 and over getting regular screening mammograms has grown rapidly since that time, and as of the most recent national SEER statistics, popular media can now report that "the most frequent breast cancer detection method is mammography," and that more than half of invasive cases are small, early-stage cancers. Breast conservation is the preferred surgical management for these cases, often followed by adjuvant systemic treatment. The combined effect of improved screening compliance and treatment advances has increased the five-year survival rate for early-stage breast cancer to 97 percent, and by 1997 had contributed to the first decrease in the overall U.S. breast cancer mortality rate in several decades.

In addition to detection and survival limitations, there are additional reasons for not over-emphasizing BSE. Surveys have shown that some women are so intimidated by examination technique and a perceived need to perform BSE correctly that they don't perform it, either regularly or at all. Another reason, suggested by some candid public health experts, is that BSE graphics are perpetuated in an effort to attract women's attention. Women may find illustrations to be more visually interesting than plain text,

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From NABCO's column  
on the Worldwide Web

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## BSE Myths and Truths ...

CONTINUED FROM PAGE 3

however, the public health goal is to offer understandable text that communicates vital medical content.

An objection to BSE sometimes voiced in the outreach setting is that unlike the earlier detection that mammograms and physician exams can offer, BSE is free. Public health agencies and private cancer organizations have become more vigilant about full and fair access to screening services in recent years, since all women need an equal chance to find and survive breast cancer, independent of their ability to pay. And with the Centers for Disease Control's breast and cervical cancer screening program for underserved women now operating in every state, not being able to afford a mammogram or a medical checkup is less frequently an excuse for skipping the potentially lifesaving exams and taking home a BSE shower card.

Even if BSE is not certain to save lives, physicians agree that it is useful for women to learn the landscape of their own breast tissue, beginning at age 20 when breast development stabilizes, and to check their own breasts regularly for lumps, skin changes and new, uneven or asymmetrical breast symptoms. NABCO's current educational messages do not urge women to "perform monthly BSE," but instead advise women to "check your own breasts regularly and learn what feels normal for you." The messages emphasize that if a woman finds something new or unusual when checking herself, she should promptly "schedule a breast exam with a doctor or nurse."

In 1998 the 17-member Board of Sponsors that supports the visible National Breast Cancer Awareness Month program each October informally agreed to emphasize mammography and CBE, and to discuss early detection methods in educational materials in descending order of their effectiveness. Some Board members (including NABCO) said they would also attempt to deemphasize BSE in written materials, to reduce the size of BSE's brochure "real estate" area, and to make it clear that BSE is never recommended as a stand-alone method of early detection. If this shift were accomplished by the influential NCI/NCAM Board of Sponsors, whose members include the American Cancer Society, the National Cancer Institute, the CDC and the Komen Foundation, even greater improvement in the U.S. breast cancer survival rate could be the result.

For a detailed list of current ABMT-supported adjuvant and advanced trials, see the NCI's new website at <http://cancertrials.nci.nih.gov>.

## ABMT Findings...

CONTINUED FROM PAGE 1

had projected, but no survival difference according to chemotherapy dose.

The Eastern Cooperative Oncology Group (ECOG) study was begun in 1990 to compare high-dose chemotherapy followed by ABMT with conventional CMF chemotherapy in almost 200 women with metastatic breast cancer who had a median age of 46. At about three years of follow-up, overall survival was 32 percent for women who had received ABMT and 38 percent for women who had received standard dose chemotherapy, results considered to be essentially the same.

The foreign studies both examined whether high-dose chemotherapy with ABMT was superior in high-risk, primary breast cancer. The Scandinavian Breast Cancer Study Group's trial compared a high-dose ABMT regimen with conventional-dose chemotherapy in over 500 women with high risk breast cancer. At almost two years of follow-up, the number of relapses and deaths revealed little difference based on dose. The small South African study used a different high-dose chemotherapy protocol in terms of both the drugs selected and the design, which unlike the U.S. studies gave no "induction" chemotherapy at the trial's outset. At nearly six years of follow-up, improved survival and lower relapse rates were observed among the 75 women who received the high-dose chemotherapy with stem cell support. All of these studies will continue to monitor relapse, survival and other outcomes and report interim data once again in several years.

It should be noted that bone marrow transplantation is not cancer therapy. Removing, storing and returning a portion of the patient's own bone marrow (or stem cells) enables oncologists to give higher-than-standard doses of cancer-killing drugs, since the return of bone marrow collected before delivering therapy accelerates the production of healthy blood cells, speeding immune system recovery. The question of whether higher doses will overcome drug resistance and produce a more durable recovery or "cure" for the patient, with safe and acceptable side effects, is the research question the trials were designed to examine.

Both donor and autologous marrow transplants have proved effective in treating several types of cancer. Based on this experience, ABMT support began to be explored in breast cancer trials, and was then quickly offered outside of trials with no data proving its efficacy. By 1995 more than 12,000 women in North America had undergone ABMT for

CONTINUED ON PAGE 5

## ABMT Findings...

CONTINUED FROM PAGE 4

breast cancer, with half contributing data to a central registry, and a far smaller number (estimated to be less than ten percent) willing to be randomized in clinical trials, thus taking the chance of receiving only standard treatment. Facing the acute discomfort and serious health risks posed by the ABMT procedure itself, most women with breast cancer who elected ABMT-supported high-dose therapy did so based largely on the hope that meeting aggressive disease with aggressive measures would prove a life-saving approach.

Armed with determination, women fought insurers in court to reverse denials of "experimental" claims; successfully lobbied in several states to mandate insurance coverage; and captured the public's heart in emotional media profiles. Wary of damage to their public images, several major U.S. insurers ultimately agreed to reimburse patients (or their families and estates) for therapy that often cost more than \$100,000.

Nearly 500 women in the U.S. will be newly diagnosed with invasive breast cancer each day in 1999, and an estimated 200 of these either are now, or later may become, candidates for treatment of high-risk, recurrent or advanced disease. The U.S. results together with the European studies have contributed important, but not definitive, outcome information which could vary with longer follow-up. Several even larger U.S. studies currently being analyzed could contradict the ASCO results when their outcomes are released in the next few years.

Recent revisions and advances in both high-dose and conventional systemic treatment mean that the ASCO results will not offer physicians and women currently weighing treatment options definitive answers that would make therapeutic choices clear-cut. As a result, breast cancer patients considering high-dose ABMT trials at the moment cannot yet achieve true informed consent. ☐

NABCO meets  
all nine standards  
of the National Charities  
Information Bureau  
August 1997

NABCO is the leading non-profit information and education resource on breast cancer and a network of over 100 national organizations. NABCO provides information on the medical progress, such as the importance of early detection and the benefits of breast self-examination and mammography. With public and corporate partners, NABCO collaborates on educational and medical programs that reach a national audience, heightening public awareness and connecting women with needed services. All contributions are tax-deductible to the extent allowable by law.

Please send us names  
of friends or colleagues  
who would like to receive  
information from NABCO.

\* If you are a NABCO  
member, an M appears  
on your address label.  
4/99

## Have You Joined NABCO?

Enclosed is my tax-deductible membership contribution, which entitles me to receive the *NABCO Resource List*, the quarterly *NABCO News*, *Conference News* twice a year and special mailings on breast cancer issues. *US funds only.*

Friend of NABCO (\$50/year)  
Non-profit group (\$100/year)  
Business (\$200/year)

e-mail NABCOinfo@aol.com  
Website www.nabco.org  
Toll-free (888) 80-NABCO

## New NABCO Video

NABCO announces the updated *On With Life: Practical Information on Living with Advanced Breast Cancer*, featuring a group of extraordinary survivors who talk about their diagnoses and offer frank advice and support. New segments feature NABCO's Board President Dr. Larry Norton, Executive Director Amy Langer and other breast cancer professionals discussing new therapies, finding needed information about treatment options, and the importance of being an active patient. The 1999 *On With Life* video was supported by an unrestricted educational grant from Novartis Oncology. To order a single VHS copy free of charge, patients and professionals may fax or e-mail NABCO.

## Mammography Results...

CONTINUED FROM PAGE 1

tions issued by the FDA.

Mammography consumers and cancer patient advocates have played a role in all aspects of MQSA since its passage, drafting initial bill language with Congressional staff, educating and testifying to assure sponsorship, and finally serving on the FDA's MQSA National Advisory Committee to shape governing regulations. Priority consumer goals expressed on the public record included assuring that women would be treated with cultural competence, sensitivity and respect; that they know how to lodge a complaint; and that they receive and understand their test results. In 1990, Medicare screening provisions required "notification in lay language" to women, supplementing technical reports sent to referring physicians. But to the dismay of women's advocates, when MQSA regulations were implemented to take precedence, the lay notification provision became optional. When direct notification did not appear in the FDA's proposed Final Regulations despite consumer testimony and letter campaigns, national organizations including NABCO successfully requested Congress to link

CONTINUED ON PAGE 6



Name \_\_\_\_\_  
Address \_\_\_\_\_  
City / State / Zip \_\_\_\_\_  
Phone / Fax \_\_\_\_\_  
E-mail \_\_\_\_\_

Make checks payable to  
National Alliance of Breast Cancer Organizations

Mail to  
NABCO, 9 East 37th Street, 10th Floor, New York, NY 10016

Telephone (212) 889-0606 Fax (212) 689-1213



## Upcoming Events

**SENTINEL LYMPH NODE MAPPING IN BREAST CANCER AND MELANOMA**  
(215) 728-5358 Philadelphia, PA May 20

**12TH ANNUAL NATIONAL CANCER SURVIVORS' DAY**  
(615) 794-3006 Nationwide June 6

**INTEGRATING COMPLEMENTARY & ALTERNATIVE THERAPIES**  
(202) 966-7338 Arlington, VA June 11-13

**FIRST ESO MILAN BREAST CANCER CONFERENCE**  
esomi@tin.it Milan, ITALY June 17-19

**WORLD CONFERENCE ON BREAST CANCER**  
(613) 549-1118 Ottawa, CANADA June 22-24

**NEW DEVELOPMENTS IN THE M  
CANCER AND MELANOMA**  
(800) 800-0666 Grand Traverse, MI June 24-26

**CDC CONFERENCE: MEETING THE CHALLENGES OF  
COMPREHENSIVE CANCER CONTROL**  
(770) 488-4226 Atlanta, GA September 8-10

**REMINDER: SUBMIT YOUR YEAR-ROUND EVENTS TO  
The NABCO Online Calendar™ at nabcoinfo@aol.com**

## Resources

Proceedings of the February 1997 American Cancer Society Workshop on Breast Cancer Treatment-Related Lymphedema are \$9.95. To order, call (888) 227-5552.

The National Cancer Institute has made a list of its currently-funded breast cancer research available. First compiled for the NCI Breast Cancer Progress Review Group; the list is at [www.nci.nih.gov/bci.html](http://www.nci.nih.gov/bci.html)

Air Lifeline is a non-profit nationwide network of licensed private pilots who provide free air transportation to patients traveling to and from treatment centers. For more information, call (877) AIR-LIFE.

Application instructions for Cycle XII funding from The Avon Breast Health Access Fund will be available from NABCO in late April, and online at [www.nabco.org](http://www.nabco.org). June 30, 1999 is the application deadline for non-profit organizations and universities to propose education and screening programs for underserved women.

## Programs

The Department of Defense Breast Cancer Research Program is seeking consumer representatives to serve on scientific review committees; applications are due May 10, 1999. Nominees must be breast cancer survivors active in advocacy or support groups and endorsed by an organization. Fax your request for forms and instructions to (301) 619-7792.

The US Postal service announced it has raised \$4.9 million with the 40 cent first class Breast Cancer research stamp since its issuance in July 1998. The 200 million stamp first printing will be supplemented by another 80 million to ensure supply through July 2000. Call (800) STAMP24 to order by phone (item #553040).

Four upcoming AVON'S BREAST CANCER 3-DAY™ events will support The Avon Breast Health Access Fund at NABCO: Chicago, June 18-20, (877) 286-6324; New York, August 27-29, (877) 286-6369; Atlanta, October 1-3, (877) 257-5553; and LA area, October 22-24, (888) 332-9286.

## Mammography Results...

CONTINUED FROM PAGE 5

mandatory "patient" notification to the passage of MQSA reauthorization, the process of making MQSA a continuing law. The FDA's regulations will now

care provider will receive the simplified report and the technical report a physician would receive.

Rules going into effect in April 1999 toughen the 1994 interim standards for personnel, equipment, quality assurance and quality control. The Final Regulations clarify a facility's responsibility to retain and transfer original mammography films to a patient's physician or directly to the patient upon written request. Further, they set standards for imaging women with breast implants and provide for public notification when a facility's performance is determined to be a health risk. Each facility is required to develop a way for consumers to voice concerns and file serious complaints, and to disclose the complaint mechanism in a manner understandable to each facility's communities of women.

## NABCO NEWS™

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National Alliance of  
Breast Cancer Organizations

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NEW YORK NY 100-05-04 MAY 19 03 1999 AX #09



Hold over for 4/15/99  
Trial Results

9 East 37th Street, 10th Floor  
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## Appendix P

Oncology News  
Volume 7, Number 1  
November 1998

### in the study

breast cancer in women at increased risk for the disease who took tamoxifen (Nolvadex), compared with placebo.

The new study will examine whether raloxifene (Evista), a selective estrogen-receptor modulator (SERM) used to treat osteoporosis, is also effective in preventing invasive breast cancer in women who have not had the disease, and whether it offers any benefits over those obtained with tamoxifen.

STAR is a randomized, double-blind study designed to include 22,000 postmenopausal women age 35 or older who are at increased risk of developing breast cancer. Participants will receive either tamoxifen at 20 mg/d or raloxifene at 60 mg/d, for 5 years. They will undergo close follow-up examinations, including a mammogram, physical exam, and gynecologic exam, on a regular basis for at least 7 years.

"We are extremely pleased at the qual-

## Breast Cancer Patients Sought for Study of Premature Menopause

■ NEW YORK—Memorial Sloan-Kettering Cancer Center and the Wake Forest University School of Medicine are seeking women recently diagnosed with breast cancer for a study of the determinants of premature menopause and its effects on quality of life. Jeanne Petrek, MD, is the principal investigator.

No blood or urine samples will be collected for this study, and patients can participate entirely through the mail. Women will fill out questionnaires and menstrual cycle diaries for the duration of the study—2½ years. Follow-up questionnaires will be sent every 6 months from the original date of enrollment, and new menstrual diaries every 3 months.

To be eligible, women must be between the ages of 18 and 45; must have been diagnosed with stage I, II, or III breast cancer in the past 8 months; and must be having regular menstrual cycles at the time of diagnosis.

For more information, please contact Joanna Winawer, research coordinator, toll-free at 877-636-7562, or by e-mail: winawer@mskcc.org. ▀

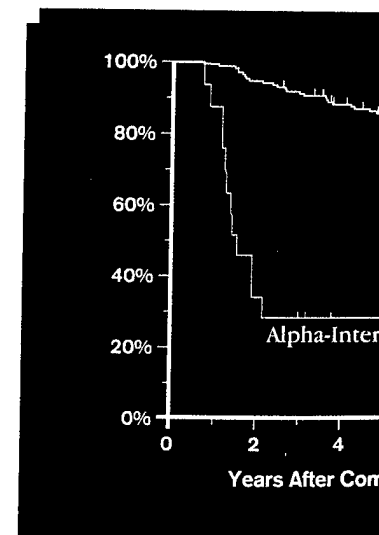
# M PENTOS

## NOW AVAILABLE

# Durable co response

➤ 90% of patients achieved a response attaining complete

➤ Nipent also produced a response in 89% of patients with initial interferon achieving complete



Relapse-free survival in patients with confirmed breast cancer (n=190). Relapse-free survival is significantly better in the Alpha-Interferon group.

Please see adjacent page for brief summary of clinical trial.  
© 1997 SuperGen, Inc., San Ramon, CA 94583

## **NEWS From the Menstrual Cycle Maintenance and Quality of Life in Young Women with Breast Cancer Study**

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**Summer 1999**

### **A Message From the Coordinating Center**

Hello from everyone at the Coordinating Center. This is the first Newsletter for the study and we hope to do it on a quarterly basis. This newsletter is for all of our participants and we would like to present information that you find useful. Regular features we are considering for the future include the following: a medical question and answer column, articles about the staff and investigators at each clinic site, and a participant corner, where you share information or inspiration, quick recipes for when you are too tired to cook, and some of the latest research being done. Please let us know what you would like to see in a newsletter.

I want to thank each of you for participating in this important study. Having participated in several studies myself, I know that finding time to fill out the questionnaires and calendars can sometimes be time consuming when so much is going on. Please know that your answers will provide important information for the future. This study is one of the first to look at issues of young women with breast cancer. To my knowledge, it is also the first that has all women scientists/surgeons/investigators. It is nice to be involved with a study of women doing research on women.

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### **New Book: Women and Cancer**

Dr. Jeanne Petrek, lead investigator in our study, has recently co-authored a book with Carolyn Runowicz, M.D., Ted Gansler, M.D. and the American Cancer Society called Women and Cancer. Dr. Petrek was kind enough to make a copy available for our participants and is enclosed. The book addresses a wide range of issues for patients and family members including: risk factors, diagnosis, treatment options and additional resource material. Cancer of the breast, cervix, endometrium and ovaries are discussed. We hope you will enjoy the book and find it useful.



## Who's Participating in the Study?

From California to Rhode Island, and Texas to Minnesota, the Menstrual Cycle Maintenance and Quality of Life Study after Breast Cancer has been enrolling young women nationwide. Currently, 389 women from 33 states are participating in the study. The study has four Clinical Centers enrolling participants: Memorial Sloan Kettering in New York, M.D. Anderson and Presbyterian Hospital in Texas and Wake Forest University Baptist Medical Center in North Carolina. The study hopes to enroll 150 additional young women before recruitment ends in December of 1999.

In our study, the average age of our participants at entry to this study was 39 years old. The youngest woman 21, and the oldest "young woman" 46. The majority of our participants are between the ages of 35 and 45. Like the American Cancer Society, only 3% of the women in our study are between the ages of 20 - 29.

The American Cancer society reports that the average age of a woman with breast cancer is 60 years old and that 77% of all breast cancers are diagnosed in women over the age of 50.

In General, the women in our study are well educated and have higher family incomes. Ninety-eight percent have completed high school, and of those, 63% have a college or graduate degree. Ninety-four percent have a family income of \$35,000 or more per year.

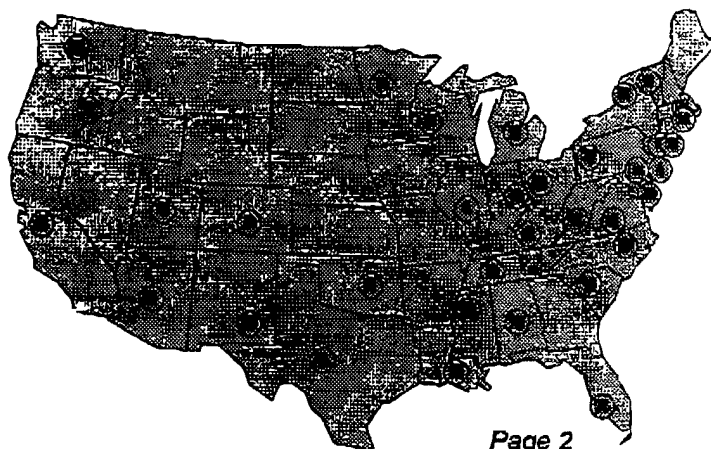
Of the 389 women in our study, 84% are white, 7% are African American, 4% are Hispanic and 5% are Asian. Seventy-

seven percent are married or have a live-in relationship, 15% have never been married and 8% are separated or divorced. Seventy-six percent of our participants have children.

The American Cancer Society suggests that five to 10% of breast cancer may be due to heredity. In our study, 11% of our participants have a family history of a mother or grandmother with breast cancer, which is slightly higher than the national average. Nine percent of our participants have a female relative who was diagnosed with breast cancer before the age of 45, and 20% of our participants have a relative who was diagnosed with breast cancer at age 45 or older.

So what do all these statistics mean? First, this information supports that our participants are similar to other breast cancer patients in many ways, which will help to generalize results to other young women with breast cancer. More importantly we have a unique opportunity to look at younger women and the issues that impact their lives, which will be different from the issues that women in their sixties and seventies face.

## Where Our Participants Are From



## **Who's Who at the Coordinating Center?**

### **Judy Bahnson - Project Manager**

Yikes . . . I hate writing about myself . . . I'm really fairly boring. When I'm not reviewing study forms, calling participants to remind them to send in their forms . . . (even when they just received them yesterday!), answering clinic staff's questions, or working on another research project, I'm usually on some band wagon or rocking some boat! I've been in research for 15 years and love it. After hours you will usually find me in the garden or in the kitchen dreaming up some new recipe or playing with my 70-pound puppy, Keplar, who is a standard poodle. You can contact me by phone (336) 716-2116, by e-mail [jbahnson@rc.phs.wfubmc.edu](mailto:jbahnson@rc.phs.wfubmc.edu) or include a note when you send in your calendars or questionnaires.

### **Kathy Dotson - Assistant Project Manager**

If things are rocking and rolling, you know Kathy's close by. Not only is she assistant project manager for two big studies, she sings in a lady's trio, (complete with poodle skirts and oxfords) performing fifties numbers and other great hits. As if that wasn't enough, in 1997 she went back to college to work on a degree in communications. Kathy does all this while being a wife and mother, and remaining active in her church. Kathy enjoys nature and says she likes to walk to clear her mind. I happen to know that she has been seen cruising her neighborhood on her new bike.

Kathy keeps track of the **Who, What, When, and Where** of the Breast Cancer study data. She knows **Who** needs forms,

**What** kind they need, **When** they need them, and **Where** they are in the system. Our tracking system is complicated and went through some changes this past winter. Fortunately, Kathy has been able to keep things straight and she and our programmer, Julia Robertson, now have things running smoothly.

Kathy enjoys the helpful and positive comments you send back with the forms and calendars. You can contact her by phone (336) 716-9486, by e-mail [kdotson@rc.phs.wfubmc.edu](mailto:kdotson@rc.phs.wfubmc.edu). I know she loves to hear from you.

### **Doris Clark - Interviewer**

Night and Day, weekdays or weekends, you'll find Doris on the phone calling our participants to remind them to send in late forms or bleeding calendars. She also works on two other research projects.

So what does this wife, mother and grandmother do for fun when she's not working? Doris loves to read . . . anything, anytime and anyplace. Her favorite books are autobiographies because she enjoys learning so much about other people's lives. She says she has been known to read and relax in the bath tub with a good book.

Doris says she looks forward to fixing the traditional big Sunday dinner and being with family. She loves spending time with her delightful three-year-old grand daughter, and her dog Sheba who is her "baby."

You can reach Doris by phone at (336) 713-8567.

## Informative Web Sites

The web-sites listed below offer information that you may find useful. If you do not have a computer, check with your local library. Most libraries now have computers and Internet access plus someone to help get you started.

### **The National Osteoporosis**

**Foundation:** [www.nof.org](http://www.nof.org)

If you have questions about osteoporosis, you will probably find answers at this site. They offer patient information, discuss news and events, and describe the benefits and risks of different treatments. In addition, they have information on medications for women who cannot use hormone replacement therapy. They also provide information on prevention and support groups.

### **The Hormone Foundation:**

[www.hormone.org](http://www.hormone.org)

This web site will send you a copy of a brochure entitled "Menopause: Treatment Options for Women Surviving Breast Cancer or Concerned about Estrogen Replacement Therapy."

### **Breast Cancer Net Newsletter:**

[www.breastcancer.net](http://www.breastcancer.net)

This site provides information on the breast cancer related news, articles and studies.

### **The American Cancer Society:**

[www.cancer.org](http://www.cancer.org)

The site offers listings of free publications, recent news articles, on and off line resources, and information on the prevention, detection and treatment of cancer.

## Too Tired to Cook?

### **Roast Beef and Asparagus Salad**

1 Bunch of fresh asparagus  
1/4 pound of 97% fat-free roast beef  
sliced very thin  
Assorted mixed salad greens  
1 green onion sliced thin  
1/4 cup chopped sweet red pepper  
Dressing -

Steam asparagus until just tender, run under cold water and drain. Roll up 3-4 stalks of asparagus in a slice of roast beef. Repeat using all of the asparagus. Arrange on top of salad greens and top with red pepper and onion and your favorite oil and vinegar dressing. Serve with warm bread for a quick dinner.

### **tlc" Tender Loving Care**

Are you looking for a new hat? The American Cancer Society has a magazine called "tlc." This magazine has one of the widest selections of hats I've seen. They have bowlers, floppy hats, swim caps, baseball and newsboy caps, berets and beanies, funky hats and sophisticated hats, and hats you can dress up or down or wear for a special evening out. They also offer a variety of special bras and swim suits.

For a free copy of the catalog call 1-800-850-9445. If you place an order, request a free copy of the videotape called A Significant Journey: Breast Cancer Survivors and the Men Who Love Them. In this video a couple who have survived cancer talk about important issues of communication, and intimacy.

\*\*\*

We welcome any questions or thoughts you have for the newsletter. Please use the space below to drop us a line. Fold the paper in half and staple or tape it closed. We have put our address on the back for your convenience.

# American Cancer Society

## **WOMEN AND CANCER**

*A Thorough and Compassionate  
Resource for Patients and  
Their Families*

Carolyn D. Runowicz, M.D.,  
Jeanne A. Petrek, M.D.,  
and  
Ted S. Gansler, M.D.

Editorial Project Director  
Dianne Partie Lange



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